CASE NO. A163682

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION 1

CENTER FOR ENVIRONMENTAL HEALTH,

Plaintiff-Appellant,

v.

PERRIGO COMPANY, et al.,

Defendants-Respondents.

Appeal from a Judgment Based on an Order Sustaining Demurrers Without Leave to Amend

Superior Court of the State of California for the County of Alameda, Case No. RG 20-054985
the Honorable Winifred Y. Smith, Presiding

APPELLANT'S APPENDIX IN LIEU OF CLERK'S TRANSCRIPT

VOLUME 1 (EXHIBITS 1-18)(AA0001-AA0383)

LEXINGTON LAW GROUP
Mark N. Todzo, State Bar No. 168389
Joseph Mann, State Bar No. 207968
503 Divisadero Street
San Francisco, CA 94117
Telephone: (415) 913-7800
Facsimile: (415) 759-4112

Attorneys for Appellant and Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

APPELLENT'S APPENDIX
CHRONOLOGICAL INDEX

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	2/19/2020	AA0025 Vol. 1	1
DEFENDANT PERRIGO COMPANY'S ANSWER TO COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	5/26/2020	AA0035 Vol. 1	2
DEFENDANT TARGET CORPORATION'S ANSWER TO COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	5/26/2020	AA0047 Vol. 1	3
FIRST AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	11/6/2020	AA0056 Vol. 1	4
SECOND AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	1/4/2021	AA0066 Vol. 1	5
DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF	2/19/2021	AA0077 Vol. 1	6
DECLARATION OF ERIKA SCHULZ RE: GOOD FAITH ATTEMPT TO MEET AND CONFER PURSUANT TO CODE OF CIVIL PROCEDURE § 430.41(a)(2)	2/19/2021	AA0114 Vol. 1	7

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DEFENDANT APOTEX CORP.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF ITS DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0122 Vol. 1	8
[PROPOSED] ORDER SUSTAINING DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0237 Vol. 1	9
NOTICE OF DEFENDANT 7-ELEVEN, INC.'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0244 Vol. 1	10
DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0251 Vol. 1	11
[PROPOSED] ORDER SUSTAINING DEFENDANT 7-ELEVEN, INC.'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	2/19/2021	AA0257 Vol. 1	12
NOTICE OF DEFENDANT TARGET CORPORATION'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0263 Vol. 1	13

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0270 Vol. 1	14
DECLARATION OF WILLIS M. WAGNER IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0289 Vol. 1	15
JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0295 Vol. 1	16
DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0309 Vol. 1	17
[PROPOSED] ORDER SUSTAINING DEFENDANT TARGET CORPORATION'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	2/25/2021	AA0315 Vol. 1	18

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES	2/25/2021	AA0325 Vol. 2	19
DECLARATION OF GREG G. SPERLA IN SUPPORT OF DEFENDANTS' DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0353 Vol. 2	20
REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS CHATTEM, INC. AND SANOFIAVENTIS U.S. LLC'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0513 Vol. 2	21
[PROPOSED] ORDER SUSTAINING DEMURRER TO SECOND AMENDED COMPLAINT	2/25/2021	AA0520 Vol. 2	22
NOTICE OF DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES LOUISIANA, LLC'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0526 Vol. 2	23
DECLARATION OF BRIAN M. LEDGER IN SUPPORT OF DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES LOUISIANA, LLC'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0533 Vol. 2	24

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
[PROPOSED] ORDER SUSTAINING DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES LOUISIANA, LLC'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	3/1/2021	AA0539 Vol. 2	25
GENERIC DEFENDANTS' JOINT MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0544 Vol. 2	26
DECLARATION OF DENNIS E. RAGLIN IN SUPPORT OF GENERIC DEFENDANTS' JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF GENERIC DEFENDANTS' DEMURRERS TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0575 Vol. 2	27
GENERIC DEFENDANTS' JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEMURRERS TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0581 Vol. 2	28
DEFENDANT GRANULES USA, INC.'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0625 Vol. 2	29
DECLARATION OF DEMURRING OR MOVING PARTY REGARDING MEET AND CONFER	3/1/2021	AA0632 Vol. 2	30

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
[PROPOSED] ORDER SUSTAINING DEFENDANT GRANULES USA, INC.'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	3/1/2021	AA0637 Vol. 2	31
NOTICE OF DEFENDANT PERRIGO COMPANY'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0643 Vol. 2	32
DECLARATION OF DEMURRING OR MOVING PARTY REGARDING MEET AND CONFER	3/1/2021	AA0650 Vol. 2	33
[PROPOSED] ORDER SUSTAINING DEFENDANT PERRIGO COMPANY'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	3/1/2021	AA0655 Vol. 2	34
PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0667 Vol. 3	35
DECLARATION OF MARK N. TODZO IN SUPPORT OF PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0713 Vol. 3	36
PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0786 Vol. 3	37

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
PROOF OF SERVICE ON PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0791 Vol. 3	38
DEFENDANT APOTEX CORP.'S REPLY IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT AND JOINDER TO REPLY OF DEFENDANT PERRIGO COMPANY	4/12/2021	AA0796 Vol. 3	39
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	4/12/2021	AA0814 Vol. 3	40
REPLY IN SUPPORT OF GENERIC MANUFACTURER DEFENDANTS' AND RETAILER DEFENDANTS' DEMURRERS TO PLAINTIFF'S SECOND AMENDED COMPLAINT	4/12/2021	AA0831 Vol. 3	41
PLAINTIFF'S OMNIBUS SURREPLY TO DEFENDANTS' REPLIES TO PLAINTIFF'S OPPOSITION TO DEMURRERS	4/19/2021	AA0857 Vol. 3	42
[TENTATIVE] ORDER SUSTAINING DEMURRERS WITH LEAVE TO AMEND	5/5/2021	AA0870 Vol. 3	43
ORDER SUSTAINING DEMURRERS TO SECOND AMENDED COMPLAINT WITH/WITHOUT LEAVE TO AMEND	5/7/2021	AA0899 Vol. 3	44

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
THIRD AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	6/9/2021	AA0934 Vol. 3	45
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES	7/21/2021	AA0951 Vol. 3	46
DECLARATION OF SEAN NEWLAND IN SUPPORT OF DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT	7/21/2021	AA0974 Vol. 3	47
REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS CHATTEM, INC. AND SANOFI AVENTIS U.S. LLC'S DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT	7/21/2021	AA0997 Vol. 3	48
[PROPOSED] ORDER SUSTAINING DEMURRER TO THIRD AMENDED COMPLAINT	7/21/2021	AA1001 Vol. 3	49
PROOF OF SERVICE ON DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT	7/21/2021	AA1004 Vol. 3	50

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
JUDGMENT OF DISMISSAL AFTER THE SUSTAINING OF DEMURRERS TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	8/11/2021	AA1007 Vol. 3	51
NOTICE OF ENTRY OF JUDGMENT	8/13/2021	AA1010 Vol. 3	52
PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1020 Vol. 3	53
DECLARATION OF MARK N. TODZO IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1043 Vol. 3	54
REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM. INC. AND SANOFI-AVENTIS US. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1060 Vol. 3	55
PROOF OF SERVICE RE PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1063 Vol. 3	56

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF DEMURRER TO THIRD AMENDED COMPLAINT	9/3/2021	AA1068 Vol. 3	57
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S RESPONSE AND OBJECTIONS TO PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE SUBMITTED IN SUPPORT OF OPPOSITION TO DEFENDANTS' DEMURRER TO THIRD AMENDED COMPLAINT	9/3/2021	AA1080 Vol. 3	58
PROOF OF SERVICE ON DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF DEMURRER TO THIRD AMENDED COMPLAINT	9/3/2021	AA1085 Vol. 3	59
NOTICE OF APPEAL	10/7/2021	AA1088 Vol. 3	60
APPELLANT'S NOTICE DESIGNATING RECORD ON APPEAL	10/7/2021	AA1101 Vol. 3	61
NOTIFICATION OF FILING NOTICE OF APPEAL	10/8/2021	AA1177 Vol. 3	62
[TENTATIVE] ORDER OVERRULING DEMURRER TO THIRD AMENDED COMPLAINT	10/25/2021	AA1181 Vol. 3	63
MINUTE ORDER RE HEARING ON DEMURRER TO THIRD AMENDED COMPLAINT	10/26/2021	AA1189 Vol. 3	64

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
CIVIL CLERK'S CERTIFICATE RE RULE 8.124 ELECTION	10/27/2021	AA1192 Vol. 3	65
ORDER RE: RULING ON SUBMITTED MATTER	12/8/2021	AA1195	66

APPELLENT'S APPENDIX
ALPHABETICAL INDEX

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
APPELLANT'S NOTICE DESIGNATING RECORD ON APPEAL	10/7/2021	AA1101 Vol. 3	61
CIVIL CLERK'S CERTIFICATE RE RULE 8.124 ELECTION	10/27/2021	AA1192 Vol. 3	65
COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	2/19/2020	AA0025 Vol. 1	1
DECLARATION OF BRIAN M. LEDGER IN SUPPORT OF DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES LOUISIANA, LLC'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0533 Vol. 2	24
DECLARATION OF DEMURRING OR MOVING PARTY REGARDING MEET AND CONFER	3/1/2021	AA0632 Vol. 2	30
DECLARATION OF DEMURRING OR MOVING PARTY REGARDING MEET AND CONFER	3/1/2021	AA0650 Vol. 2	33

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DECLARATION OF DENNIS E. RAGLIN IN SUPPORT OF GENERIC DEFENDANTS' JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF GENERIC DEFENDANTS' DEMURRERS TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0575 Vol. 2	27
DECLARATION OF ERIKA SCHULZ RE: GOOD FAITH ATTEMPT TO MEET AND CONFER PURSUANT TO CODE OF CIVIL PROCEDURE § 430.41(a)(2)	2/19/2021	AA0114 Vol. 1	7
DECLARATION OF GREG G. SPERLA IN SUPPORT OF DEFENDANTS' DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0353 Vol. 2	20
DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0251 Vol. 1	11
DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0309 Vol. 1	17

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DECLARATION OF MARK N. TODZO IN SUPPORT OF PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0713 Vol. 3	36
DECLARATION OF MARK N. TODZO IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1043 Vol. 3	54
DECLARATION OF SEAN NEWLAND IN SUPPORT OF DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT	7/21/2021	AA0974 Vol. 3	47
DECLARATION OF WILLIS M. WAGNER IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0289 Vol. 1	15
DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF	2/19/2021	AA0077 Vol. 1	6

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DEFENDANT APOTEX CORP.'S REPLY IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT AND JOINDER TO REPLY OF DEFENDANT PERRIGO COMPANY	4/12/2021	AA0796 Vol. 3	39
DEFENDANT APOTEX CORP.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF ITS DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0122 Vol. 1	8
DEFENDANT GRANULES USA, INC.'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0625 Vol. 2	29
DEFENDANT PERRIGO COMPANY'S ANSWER TO COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	5/26/2020	AA0035 Vol. 1	2
DEFENDANT TARGET CORPORATION'S ANSWER TO COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	5/26/2020	AA0047 Vol. 1	3
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES	2/25/2021	AA0325 Vol. 2	19

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES	7/21/2021	AA0951 Vol. 3	46
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	4/12/2021	AA0814 Vol. 3	40
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF DEMURRER TO THIRD AMENDED COMPLAINT	9/3/2021	AA1068 Vol. 3	57
DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S RESPONSE AND OBJECTIONS TO PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE SUBMITTED IN SUPPORT OF OPPOSITION TO DEFENDANTS' DEMURRER TO THIRD AMENDED COMPLAINT	9/3/2021	AA1080 Vol. 3	58
DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0270 Vol. 1	14

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
FIRST AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	11/6/2020	AA0056 Vol. 1	4
GENERIC DEFENDANTS' JOINT MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0544 Vol. 2	26
GENERIC DEFENDANTS' JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEMURRERS TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0581 Vol. 2	28
JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0295 Vol. 1	16
JUDGMENT OF DISMISSAL AFTER THE SUSTAINING OF DEMURRERS TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	8/11/2021	AA1007 Vol. 3	51
MINUTE ORDER RE HEARING ON DEMURRER TO THIRD AMENDED COMPLAINT	10/26/2021	AA1189 Vol. 3	64
NOTICE OF APPEAL	10/7/2021	AA1088 Vol. 3	60

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
NOTICE OF DEFENDANT 7-ELEVEN, INC.'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0244 Vol. 1	10
NOTICE OF DEFENDANT PERRIGO COMPANY'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0643 Vol. 2	32
NOTICE OF DEFENDANT TARGET CORPORATION'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0263 Vol. 1	13
NOTICE OF DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES LOUISIANA, LLC'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	3/1/2021	AA0526 Vol. 2	23
NOTICE OF ENTRY OF JUDGMENT	8/13/2021	AA1010 Vol. 3	52
NOTIFICATION OF FILING NOTICE OF APPEAL	10/8/2021	AA1177 Vol. 3	62
ORDER RE: RULING ON SUBMITTED MATTER	12/8/2021	AA1195	66
ORDER SUSTAINING DEMURRERS TO SECOND AMENDED COMPLAINT WITH/WITHOUT LEAVE TO AMEND	5/7/2021	AA0899 Vol. 3	44

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0667 Vol. 3	35
PLAINTIFF'S OMNIBUS SURREPLY TO DEFENDANTS' REPLIES TO PLAINTIFF'S OPPOSITION TO DEMURRERS	4/19/2021	AA0857 Vol. 3	42
PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1020 Vol. 3	53
PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0786 Vol. 3	37
PROOF OF SERVICE ON DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S NOTICE OF DEMURRER AND DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT	7/21/2021	AA1004 Vol. 3	50
PROOF OF SERVICE ON DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF DEMURRER TO THIRD AMENDED COMPLAINT	9/3/2021	AA1085 Vol. 3	59
PROOF OF SERVICE ON PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' DEMURRERS	3/29/2021	AA0791 Vol. 3	38

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
PROOF OF SERVICE RE PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM, INC. AND SANOFI-AVENTIS U.S. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1063 Vol. 3	56
[PROPOSED] ORDER SUSTAINING DEFENDANT 7-ELEVEN, INC.'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	2/19/2021	AA0257 Vol. 1	12
[PROPOSED] ORDER SUSTAINING DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/19/2021	AA0237 Vol. 1	9
[PROPOSED] ORDER SUSTAINING DEFENDANT GRANULES USA, INC.'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	3/1/2021	AA0637 Vol. 2	31
[PROPOSED] ORDER SUSTAINING DEFENDANT PERRIGO COMPANY'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	3/1/2021	AA0655 Vol. 2	34
[PROPOSED] ORDER SUSTAINING DEFENDANT TARGET CORPORATION'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	2/25/2021	AA0315 Vol. 1	18

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
[PROPOSED] ORDER SUSTAINING DEFENDANTS DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES LOUISIANA, LLC'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND	3/1/2021	AA0539 Vol. 2	25
[PROPOSED] ORDER SUSTAINING DEMURRER TO SECOND AMENDED COMPLAINT	2/25/2021	AA0520 Vol. 2	22
[PROPOSED] ORDER SUSTAINING DEMURRER TO THIRD AMENDED COMPLAINT	7/21/2021	AA1001 Vol. 3	49
REPLY IN SUPPORT OF GENERIC MANUFACTURER DEFENDANTS' AND RETAILER DEFENDANTS' DEMURRERS TO PLAINTIFF'S SECOND AMENDED COMPLAINT	4/12/2021	AA0831 Vol. 3	41
REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS CHATTEM, INC. AND SANOFI AVENTIS U.S. LLC'S DEMURRER TO PLAINTIFF'S THIRD AMENDED COMPLAINT	7/21/2021	AA0997 Vol. 3	48
REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS CHATTEM, INC. AND SANOFIAVENTIS U.S. LLC'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT	2/25/2021	AA0513 Vol. 2	21

DOCUMENT	DATE	AA PAGE / VOL.	EXH. NO.
REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS CHATTEM. INC. AND SANOFI-AVENTIS US. LLC'S DEMURRER TO THIRD AMENDED COMPLAINT	8/20/2021	AA1060 Vol. 3	55
SECOND AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES	1/4/2021	AA0066 Vol. 1	5
[TENTATIVE] ORDER OVERRULING DEMURRER TO THIRD AMENDED COMPLAINT	10/25/2021	AA1181 Vol. 3	63
[TENTATIVE] ORDER SUSTAINING DEMURRERS WITH LEAVE TO AMEND	5/5/2021	AA0870 Vol. 3	43

Exhibit 1

LEXINGTON LAW GROUP
Mark N. Todzo (State Bar No. 168389)
Joseph Mann (State Bar No. 207968)
503 Divisadero Street
San Francisco, CA 94117
Telephone: (415) 913-7800
Facsimile: (415) 759-4112
mtodzo@lexlawgroup.com
jmann@lexlawgroup.com

Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; and DOES 1 through 20, inclusive,

Defendants.

Case No. RG 20054985

COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

Health & Safety Code § 25249.6, *et seq.*

(Other)

Plaintiff Center for Environmental Health, in the public interest, based on information and belief and investigation of counsel, except for information based on knowledge, hereby makes the following allegations:

INTRODUCTION

1. This Complaint seeks to remedy Defendants' continuing failure to warn individuals in California that they are being exposed to n-nitrosodimethylamine ("NDMA"), a chemical known to the State of California to cause cancer. Such exposures have occurred, and continue to occur, through the manufacture, distribution, sale, and use of over-the-counter acid reducing medications containing ranitidine (the "Products"). Individuals in California are exposed to NDMA when they use the Products.

2. Under California's Proposition 65, Health & Safety Code § 25249.5, *et seq.*, it is unlawful for businesses to knowingly and intentionally expose individuals in California to chemicals known to the State to cause cancer without providing clear and reasonable warnings to such individuals. Defendants introduce Products containing significant quantities of NDMA into the California marketplace, thereby exposing users of their Products to NDMA.

3. Despite the fact that Defendants expose individuals to NDMA, Defendants provide no clear and reasonable warnings about the carcinogenic hazards associated with NDMA exposure. Defendants' conduct thus violates the warning provision of Proposition 65, Health & Safety Code § 25249.6.

PARTIES

4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("CEH") is a non-profit corporation dedicated to protecting the public from environmental health hazards and toxic exposures. CEH is based in Oakland, California and incorporated under the laws of the State of California. CEH is a "person" within the meaning of Health & Safety Code § 25249.11(a) and brings this enforcement action in the public interest pursuant to Health & Safety Code § 25249.7(d). CEH is a nationally recognized non-profit environmental advocacy group that has prosecuted a large number of Proposition 65 cases in the public interest. These cases have resulted in significant public benefit, including the reformulation of thousands of products to

remove toxic chemicals and to make them safer. CEH also provides information to Californians about the health risks associated with exposure to hazardous substances, where manufacturers and other responsible parties fail to do so.

5. Defendant PERRIGO COMPANY is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant PERRIGO COMPANY manufactures, distributes, and/or sells the Products for sale and use in California.

6. Defendant TARGET CORPORATION is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant TARGET CORPORATION manufactures, distributes, and/or sells the Products for sale and use in California.

7. DOES 1 through 20 are each a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. DOES 1 through 20 manufacture, distribute, and/or sell the Products for sale and use in California. Defendants PERRIGO COMPANY; TARGET CORPORATION; and DOES 1 through 20 are collectively referred to herein as "Defendants."

8. The true names of DOES 1 through 20 are either unknown to CEH at this time or the applicable time period before which CEH may file a Proposition 65 action has not run. When their identities are ascertained or the applicable time period before which CEH may file a Proposition 65 action has run, the Complaint shall be amended to reflect their true names.

JURISDICTION AND VENUE

9. The Court has jurisdiction over this action pursuant to Health & Safety Code § 25249.7, which allows enforcement in any court of competent jurisdiction, and pursuant to California Constitution Article VI, Section 10, because this case is a cause not given by statute to other trial courts.

10. This Court has jurisdiction over Defendants because each is a business entity that does sufficient business, has sufficient minimum contacts in California, or otherwise intentionally avails itself of the California market through the sale, marketing, or use of the Products in California and/or by having such other contacts with California so as to render the exercise of

jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

11. Venue is proper in Alameda County Superior Court because one or more of the violations arise in the County of Alameda.

BACKGROUND FACTS

12. The People of the State of California have declared by initiative under Proposition 65 their right "[t]o be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm." Proposition 65, § 1(b).

13. To effectuate this goal, Proposition 65 prohibits exposing people to chemicals listed by the State of California as known to cause cancer, birth defects, or other reproductive harm above certain levels without a "clear and reasonable warning" unless the business responsible for the exposure can prove that it fits within a statutory exemption. Health & Safety Code § 25249.6 states, in pertinent part:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . .

14. On October 1, 1987, the State of California officially listed NDMA as a chemical known to cause cancer. 27 Cal. Code Regs. ("C.C.R.") § 27001(b). On October 1, 1988, one year after it was listed as a chemical known to cause cancer, NDMA became subject to the clear and reasonable warning requirement regarding carcinogens under Proposition 65. 27 C.C.R. § 27001(b); Health & Safety Code § 25249.10(b).

15. NDMA is a nitrosamine, a class of chemical compounds that form when nitrates and amino acids combine. NDMA is used in laboratory research to induce tumors in experimental animals. Nitrosamines such as NDMA can also form during the manufacturing process of certain drug products, such as those containing ranitidine.

16. Defendants' Products contain sufficient quantities of NDMA such that individuals are exposed to NDMA through the average use of the Products. The primary route of exposure is

through ingestion when individuals use the Products. These exposures occur everywhere throughout California where the Products are used.

17. No clear and reasonable warning is provided with the Products regarding the carcinogenic hazards of NDMA.

18. The Products are popular over-the-counter medications for treatment of heartburn. They are part of a class of acid reducing products known as H2 blockers, because they block the formation of acid in the stomach. There are a number of other H2 blockers available for over-the-counter sale that do not contain ranitidine. The failure to provide warnings regarding the carcinogenicity of NDMA in Ranitidine Products is of particular concern in light of evidence that ingestion of NDMA causes cancer and the alternative products on the market that do not contain NDMA.

19. Any person acting in the public interest has standing to enforce violations of Proposition 65 provided that such person has supplied the requisite public enforcers with a valid 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the action within such time. Health & Safety Code § 25249.7(d).

20. More than sixty days prior to naming each Defendant in this lawsuit, CEH provided a 60-Day "Notice of Violation of Proposition 65" to the California Attorney General, to the District Attorneys of every county in California, to the City Attorneys of every California city with a population greater than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code § 25249.7(d) and 27 C.C.R. § 25903(b), each Notice included the following information: (1) the name and address of each violator; (2) the statute violated; (3) the time period during which violations occurred; (4) specific descriptions of the violations, including (a) the routes of exposure to NDMA from the Products, and (b) the specific type of Products sold and used in violation of Proposition 65; and (5) the name of the specific Proposition 65-listed chemical that is the subject of the violations described in each Notice.

21. CEH also sent a Certificate of Merit for each Notice to the California Attorney General, to the District Attorneys of every county in California, to the City Attorneys of every California city with a population greater than 750,000, and to each of the named Defendants. In

compliance with Health & Safety Code § 25249.7(d) and 11 C.C.R. § 3101, each Certificate certified that CEH's counsel: (1) has consulted with one or more persons with relevant and appropriate experience or expertise who reviewed facts, studies, or other data regarding the exposures to NDMA alleged in each Notice; and (2) based on the information obtained through such consultations, believes that there is a reasonable and meritorious case for a citizen enforcement action based on the facts alleged in each Notice. In compliance with Health & Safety Code § 25249.7(d) and 11 C.C.R. § 3102, each Certificate served on the Attorney General included factual information – provided on a confidential basis – sufficient to establish the basis for the Certificate, including the identity of the person(s) consulted by CEH's counsel and the facts, studies, or other data reviewed by such persons.

22. None of the public prosecutors with the authority to prosecute violations of Proposition 65 has commenced and/or is diligently prosecuting a cause of action against Defendants under Health & Safety Code § 25249.5, *et seq*., based on the claims asserted in each of CEH's Notices.

23. Defendants both know and intend that individuals will use the Products, thus exposing them to NDMA.

24. Under Proposition 65, an exposure is "knowing" where the party responsible for such exposure has:

> knowledge of the fact that a[n] . . . exposure to a chemical listed pursuant to [Health & Safety Code § 25249.8(a)] is occurring. No knowledge that the . . . exposure is unlawful is required.

27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See*, *e.g.*, Final Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2, § 12601).

25. As companies that manufacture, import, distribute, and/or sell the Products for use in the California marketplace, Defendants know or should know that the Products contain NDMA and that individuals who use the Products will be exposed to NDMA. The NDMA exposures to individuals who use the Products are a natural and foreseeable consequence of Defendants' placing the Products into the stream of commerce.

26. Defendants have also been informed of the NDMA exposures caused by their Products pursuant to the 60-Day Notice of Violation and accompanying Certificate of Merit served on them by CEH.

27. Defendants have also been informed of the NDMA exposures caused by their Products by a series of widely-publicized recalls of Products from the national marketplace due to the presence of NDMA, which commenced in September 2019. These recalls were based on findings of significant quantities of NDMA by an independent laboratory in Products that were already made available for sale to consumers. Following up on these recalls, the U.S. Food and Drug Administration issued a public alert that (1) set forth the results of the agency's testing in Products, which also found NDMA in all Products tested, (2) instructed companies selling Products to perform their own testing for NDMA in Products, and (3) advised such companies to recall their Products if testing confirmed the presence of NDMA above certain federal levels.

28. Nevertheless, Defendants continued to expose individuals to NDMA without prior clear and reasonable warnings regarding the carcinogenic hazards of NDMA even after the publicity and recalls.

29. CEH has engaged in good-faith efforts to resolve the claims alleged herein prior to filing this Complaint.

30. Any person "violating or threatening to violate" Proposition 65 may be enjoined in any court of competent jurisdiction. Health & Safety Code § 25249.7. "Threaten to violate" is defined to mean "to create a condition in which there is a substantial probability that a violation will occur." Health & Safety Code § 25249.11(e). Proposition 65 provides for civil penalties not to exceed $2,500 per day for each violation of Proposition 65.

FIRST CAUSE OF ACTION
(Violations of Health & Safety Code § 25249.6)

31. CEH realleges and incorporates by reference as if specifically set forth herein Paragraphs 1 through 30, inclusive.

32. By placing the Products into the stream of commerce, Defendants are each a person in the course of doing business within the meaning of Health & Safety Code § 25249.11.

33. NDMA is a chemical listed by the State of California as known to cause cancer.

34. Defendants know that ordinary use of the Products will expose users of their Products to NDMA. Defendants intend that the Products be used in a manner that results in exposures to NDMA.

35. Defendants have failed, and continue to fail, to provide clear and reasonable warnings regarding the carcinogenicity of NDMA to users of the Products.

36. By committing the acts alleged above, Defendants have at all times relevant to this Complaint violated Proposition 65 by knowingly and intentionally exposing individuals to NDMA without first giving clear and reasonable warnings to such individuals regarding the carcinogenicity of NDMA.

PRAYER FOR RELIEF

Wherefore, CEH prays for judgment against Defendants as follows:

1. That the Court, pursuant to Health & Safety Code § 25249.7(a), preliminarily and permanently enjoin Defendants from offering Products for sale in California without providing prior clear and reasonable warnings, as CEH shall specify in further application to the Court;

2. That the Court, pursuant to Health & Safety Code § 25249.7(a), order Defendants to take action to stop ongoing unwarned exposures to NDMA resulting from use of Products sold by Defendants, as CEH shall specify in further application to the Court;

3. That the Court, pursuant to Health & Safety Code § 25249.7(b), assess civil penalties against each of the Defendants in the amount of $2,500 per day for each violation of Proposition 65 according to proof;

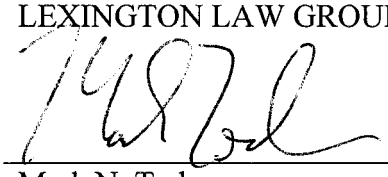
4. That the Court, pursuant to Code of Civil Procedure § 1021.5 or any other applicable theory, grant CEH its reasonable attorneys' fees and costs of suit; and

5. That the Court grant such other and further relief as may be just and proper.

Dated: February 19, 2020

Respectfully submitted,

LEXINGTON LAW GROUP



Mark N. Todzo
Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

Exhibit 2

Dennis Raglin (SBN 179261)
draglin@steptoe.com
Danielle Vallone (SBN 302497)
dvallone@steptoe.com
STEPTOE & JOHNSON LLP
633 West Fifth Street, Suite 1900
Los Angeles, California 90071
Telephone: 213 439 9400
Facsimile: 213 439 9599

Attorneys for Defendant
PERRIGO COMPANY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; and DOES 1 to 20, inclusive,

Defendant.

Case No. RG 20054985

Hon. Jeffrey Brand
Department 22

ANSWER TO COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

Complaint Filed: February 19, 2020

Defendant PERRIGO COMPANY (hereinafter "Perrigo") answers the unverified Complaint of Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("Plaintiff") as follows:

GENERAL DENIAL

1. Pursuant to Section 431.30 of the California Code of Civil Procedure, Perrigo denies each and every and all of the allegations of the Complaint, and each cause of action thereof, and denies that Plaintiff sustained damages in the sum or sums alleged or in any other sum, or at all.

///

///

///

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

2. Plaintiff's Complaint, and each cause of action therein, does not state facts sufficient to constitute a cause of action against Perrigo.

SECOND AFFIRMATIVE DEFENSE

(Statutory Exemption)

3. Pursuant to California Health and Safety Code§ 25249.10 subd. (c), any exposures as alleged in the Complaint are exempt from the warning requirement of California Health and Safety Code § 25249.6 because, based on evidence and standards of comparable scientific validity, as to those which form the scientific basis for the listing pursuant to California Health and Safety Code§ 25239.8 subd. (a), and California Code of Regulations, Title27, §§25000 *et seq*., the alleged exposures pose no significant risk of cancer.

THIRD AFFIRMATIVE DEFENSE

(No Knowing or Intentional Exposure)

4. Perrigo has not violated California Health and Safety Code 25249.6 with respect to the Products alleged in the Complaint because, in the course of doing business in California, Perrigo has not knowingly or intentionally exposed any individual in the state to any significant amount of the listed Proposition 65 chemical in the Products as they were withdrawn from California before Plaintiff filed the Complaint. There was therefore no knowing or intentional sale in California of the Products and thus no exposure, making Plaintiff's Complaint moot and its allegations that Perrigo continues to exposure Californians to the chemical through sale of the Products demonstrably false.

FOURTH AFFIRMATIVE DEFENSE

(Naturally Occurring)

5. Perrigo has not violated California Health and Safety Code § 25249.6 because the listed chemical, the exposure of which Plaintiff alleges constitutes a violation, was naturally occurring, including in water, in the identified Products and, therefore, there is no exposure to such chemical. (California Code of Regulations, Title 27, Section 25501).

FIFTH AFFIRMATIVE DEFENSE

(Statute of Limitations)

6. Plaintiffs' Complaint is barred by the one-year statute of limitations set forth in *Shamisan v. Atlantic Richfield*, (2003) 107 Cal.App.4th 967. Plaintiff's Complaint is further barred and/or limited by the applicable statutes of limitations, including but not limited to, Code of Civil Procedure §§ 338(d), 338(h), 340(1), 340(2), 340(3) and/or 343.

SIXTH AFFIRMATIVE DEFENSE

(Laches)

7. Perrigo alleges that Plaintiff is barred by the doctrine of laches from asserting the claims in its Complaint.

SEVENTH AFFIRMATIVE DEFENSE

(Estoppel and Waiver)

8. The claims in Plaintiff's Complaint are barred by the doctrines of estoppel and / or waiver.

EIGHTH AFFIRMATIVE DEFENSE

(First Amendment)

9. Plaintiff's Complaint is barred in that Proposition 65 and its implementing regulations to the noticed Products violate Perrigo's right of free speech, in violation of the First Amendment to the United States Constitution, applied to the states by and through the Fourteenth Amendment, and also as guaranteed by the California Constitution, Article I, Section 2(a), as such warnings would be compelled false and misleading speech.

NINTH AFFIRMATIVE DEFENSE

(Due Process Violation)

10. To the extent Plaintiff purports to seek relief on behalf of members of the general public who have suffered no damages, the Complaint and each of its claims for relief therein violate Perrigo's right to due process under the California and United States Constitutions Amendment V, applied to the states by the Fourteenth Amendment, as the Act and its implementing regulations fail to provide fair notice regarding when or how Perrigo is required to

provide Proposition 65 warnings to consumers who use its Products. Perrigo further alleges that the private enforcement provisions of Health & Safety Code § 25249.7(d) are unconstitutional on their face and as exercised by Plaintiff because said provisions encroach on the constitutional duties of the California Attorney General to ensure that the laws of the state are uniformly enforced. Hence, this results in infringement of the separation of powers of Article III, Section 3 of California's Constitution. In addition, Proposition 65 violates due process and the separation of powers because the law improperly shifts the decision on what constitutes an appropriate and quantifiable exposure level of the alleged chemical in question from the legislative to the executive branch and gives that power to the judiciary branch. Health and Safety Code § 25249.10(c) and its implementing regulations do not set forth an objective standard for a determination but instead require the Court to make the determination of the standard and safe exposure as to each product after trial.

TENTH AFFIRMATIVE DEFENSE

(Federal Preemption – Conflict with Federal Regulation of OTC Drugs)

11. Perrigo alleges that the Complaint, and each claim for relief therein, is preempted under the Supremacy Clause of the United States Constitution and controlling case law. The United Stated Food and Drug Administration ("FDA") has enacted regulations providing for the regulation of drugs such as the Products named in the Complaint. Perrigo, as a generic drug manufacturer, is bound by federal regulation with respect to the content of its labeling that provide that Perrigo's generic drug products must have the same labeling as the brand-name reference listed drug's labeling, and it cannot satisfy both this federal law and regulation imposing this "duty of sameness" and state law that mandates a conflicting Proposition 65 warning. (*PLIVA v. Mensing*, 564 U.S. 604 (2011).)

ELEVENTH AFFIRMATIVE DEFENSE

(Federal Preemption – Misbranding of OTC Drugs)

12. Perrigo alleges that the Complaint, and each claim for relief therein, is barred by the Supremacy Clause of the United States Constitution and controlling federal law and regulations. As required by Congress, the FDA has enacted regulations prohibiting misbranding

of over-the-counter ("OTC") drugs. Proposition 65, which requires placing cancer and reproductive toxicity warnings on all OTC drugs where any detectible level of a listed chemical is present, results in misbranding of OTC drugs that have been deemed safe under national and international standards. As such, the warnings Plaintiff seeks to impose are misleading and constitute misbranding under the Food, Drug and Cosmetics Act. Further, the *ad hoc* manner in which acceptable, no-warning levels are negotiated (only after enforcement action has been brought) supports the conclusion that warnings on Products containing less that the negotiated level of a listed chemical are in fact unnecessary to protect the public from any significant health risk and result in misbranding of those Products. Through its actions as a Proposition 65 enforcer, Plaintiff seeks to impose conditions and standards on the Products in a manner that usurps both FDA's authority and Congressional mandates. The California Supreme Court has found that Proposition 65 warnings on OTC drugs constitute misbranding and are barred. (*Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910.)

TWELFTH AFFIRMATIVE DEFENSE

(Conflict and Preemption by State Law)

13. Perrigo alleges that the application of Proposition 65 and its implementing regulations to Perrigo Products irreconcilably conflicts with and is preempted by state statutes and regulations, including the Sherman Food, Drug and Cosmetic Act, California Health & Safety Act and the California Commercial Code section 1101 et seq. (sales of goods).

THIRTEENTH AFFIRMATIVE DEFENSE

(Equal Protection)

14. Perrigo alleges that Proposition 65 and its implementing regulations violate Perrigo's right to equal protection of the laws of the state of California and the United States because, among other things, the Act and its implementing regulations fail to establish clear, reasonable, quantified and certain standards and authorizes enforcers to initiate enforcement at any detectible level of listed chemicals and impermissibly shifts the burden of proof to the defendant to both establish and quantify the applicable Proposition 65 standard as well as to prove that their Products do not exceed the court's determination of such quantified standard.

FOURTEENTH AFFIRMATIVE DEFENSE

(Commerce Clause)

15. Perrigo alleges that the Complaint is barred in that Plaintiff seeks to apply Proposition 65 and its implementing regulations in such a manner so as to impose an undue burden on interstate commerce in violation of the United States Constitution by requiring through this law and its regulations specific requirements for sales of Products to California not required for Products to all other states in the Country.

FIFTEENTH AFFIRMATIVE DEFENSE

(Void for Vagueness)

16. Perrigo alleges that Proposition 65 and its implementing regulations are unconstitutionally vague. The law impermissibly delegates to the judicial the task of developing and quantifying the applicable standards, as well as determining whether such standards were violated. It is thus impossible for Perrigo to know before the Court's determination, and after expert testimony and evidence is weighed and admitted, whether a warning is required. As such, Proposition 65 violates Perrigo's due process and equal protection rights under the United States and California Constitutions.

SIXTEENTH AFFIRMATIVE DEFENSE

(Res Judicata)

17. Perrigo and PBM allege that the Complaint, and each cause of action therein, is precluded by the doctrines of *res judicata*.

SEVENTEENTH AFFIRMATIVE DEFENSE

(Collateral Estoppel)

18. Plaintiff's Complaint, and each cause of action therein, is barred by the doctrine of collateral estoppel. Plaintiff requests the Court grant injunctive relief, but there is none to grant as the issue has already been decided. The Products at issue were withdrawn from sale at the request of the FDA in September 2019, before Plaintiff filed this Complaint. Perrigo complied and the Products have not been sold in California since. On April 1, 2020, FDA reiterated its withdrawal order on the sale of these Products and Perrigo has neither attempted to, or stated it

will, sell them in California. Plaintiff's Complaint alleging an ongoing violation of Proposition 65 is demonstrably false in that there is no ongoing violation and Plaintiff has no basis on which to seek injunctive relief under Proposition 65, making the filing of this Complaint both questionable and moot.

EIGHTEENTH AFFIRMATIVE DEFENSE

(Unclean Hands)

19. Perrigo alleges that the Plaintiff's Complaint, and all claims contained therein, are barred under the doctrine of unclean hands.

NINETEENTH AFFIRMATIVE DEFENSE

(Attorneys' Fees Barred)

20. Perrigo alleges that Plaintiff is barred from any recovery for attorneys' fees as sought in its Complaint because Plaintiff has failed to meet the requirements of California Code of Civil Procedure § 1021.5, and is litigating this matter for its financial gain and not in the public interest.

TWENTIETH AFFIRMATIVE DEFENSE

(No Basis for Equitable or Injunctive Relief)

21. Plaintiff is not entitled to equitable relief and no threat of harm exists to support a grant of preliminary injunctive relief, whether under Proposition 65 and its interpretive regulations or under California law.

TWENTY-FIRST AFFIRMATIVE DEFENSE

(No Basis for Monetary Damages or Penalties)

22. Both because Plaintiff has not been injured and because there exists no ongoing violation pursuant to Proposition 65, Plaintiff is not entitled to monetary damages or penalties under the law or its interpretive regulations.

TWENTY-SECOND AFFIRMATIVE DEFENSE

(Not Justiciable)

23. Perrigo alleges the claims in Plaintiff's Complaint are barred in that Plaintiff is not proceeding in "the public interest" as required by California Health and Safety Code § 25249.7

(*See Consumer Advocacy Group v. ExxonMobil Corp.* (2008) 168 Cal.App.4th 675, 692-693.)

TWENTY-THIRD AFFIRMATIVE DEFENSE

(Lack of Standing to Pursue Case)

24. Some or all of Plaintiff's claims alleged in its Complaint are barred, and / or cannot now be maintained, because Plaintiff failed to fully comply with, or can no longer meet, the requirements set forth in California Health & Safety Code § 25249.6, CCR, Title 11, § 3000, *et. seq.*, and CCR Title 27 § 25102, *et seq.*, as the FDA ordered the Products withdrawn from the market in September 2019, a year before the filing of the Complaint, and Perrigo complied. Plaintiff therefore has no standing to continue to pursue the case.

TWENTY-FOURTH AFFIRNMATIVE DEFENSE

(Inadequate Notice of Violation)

25. Plaintiff's Complaint is barred because it is based on an invalid Notice of Violation, filed after the FDA ordered the Products withdrawn from sale in California, and after Perrigo complied, such that Plaintiff's Notice – filed with the Attorney General – was incorrect in alleging Perrigo was at the time of the filing exposing Californians to the chemical in question, meaning there was no violation for which injunctive relief could be sought.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Misuse, Alteration of Product)

26. Plaintiff's claims are barred in whole or in part to the extent that Plaintiff, or the general public it purports to represent, misused, abused, or altered the noticed Products in a manner not reasonably foreseeable to Perrigo, thereby causing or contributing to any alleged loss, injury, exposure or harm asserted by Plaintiff in this action.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Failure to Join Necessary and/or Indispensable Parties)

27. Perrigo alleges that the Complaint is barred as it fails to name or join all necessary parties pursuant to Code of Civil Procedure §§ 389 and 430.10(d).

///

///

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Cancer Claim Barred)

28. Perrigo alleges that Plaintiff's claims as set forth in its Complaint alleging that the noticed Products expose consumers to an alleged carcinogen are barred in that the evidence establishes that the amount of the noticed chemical in the Products is significantly under the established safe harbor level for the carcinogenic effect of n-nitrosodimethylamine (NDMA) established by the State of California.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

29. Perrigo hereby gives notice that it intends to rely upon such other and further defenses as may become available or appear during the discovery proceedings in this case and hereby reserves his rights to amend this answer to assert any such defense.

WHEREFORE, Perrigo prays as follows:

1. That Plaintiff take nothing by its Complaint on file herein;

2. For costs of suit incurred herein;

3. That if Perrigo is found liable, that the degree of responsibility and liability be determined and that Perrigo be held liable only for that portion of the total damages in proportion to liability for the same;

4. For attorney fees and costs as allowed by law; and

5. For such other and further relief as the Court may deem just and proper.

Dated: May 26, 2020

STEPTOE & JOHNSON LLP

By: _____

Dennis Raglin
Danielle Vallone
Attorneys for Defendant
PERRIGO COMPANY

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **May 26, 2020**, I served the following listed document(s), by method indicated below, on the parties in this action: **ANSWER TO COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing ☐ the original / ☐ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents. **Note:** Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
☐ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
☐ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **May 26, 2020,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center For Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo mtodzo@lexlawgroup.com Joseph Mann jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Lauren Shoor lauren.shoor@nortonrosefulbright.com Norton Rose Fulbright US LLP 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225	Attorneys for Defendant Target Corporation

Exhibit 3

NORTON ROSE FULBRIGHT US LLP
JEFFREY B. MARGULIES (BAR NO. 126002)
LAUREN A. SHOOR (BAR NO. 280788)
ANDY GUO (BAR NO. 307824)
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494
jeff.margulies@nortonrosefulbright.com
lauren.shoor@nortonrosefulbright.com
andy.guo@nortonrosefulbright.com

Attorneys for Defendant
TARGET CORPORATION

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; and DOES 1 through 20, inclusive,

Defendant.

Case No. RG20054985

Assigned For All Purposes To The Honorable Jeffrey Brand, Dept. 22

DEFENDANT TARGET CORPORATION'S ANSWER TO PLAINTIFF'S COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

COMES NOW Defendant Target Corporation ("Defendant"), for itself and no other defendant, and in response to Plaintiff Center for Environmental Health's ("Plaintiff") Complaint for Injunctive Relief and Civil Penalties ("Complaint"), alleges, denies and avers as follows:

GENERAL DENIAL

1. Pursuant to Code of Civil Procedure section 431.30, Defendant denies the allegations of Plaintiff's Complaint, and each cause of action, and each paragraph in each cause of action, and each and every part thereof.

2. Defendant further denies that, by reason of any act or omission, fault, conduct, or liability on part of this answering Defendant, whether negligent, careless, unlawful, or whether as alleged as otherwise, it "knowingly and intentionally" exposed any persons to chemicals listed pursuant to 27 Cal. Code Regs. section 27001 without first providing "clear and reasonable warning" pursuant to Health & Safety Code section 25249.6, or that Defendant is liable in any manner for any penalties or other costs, or that injunctive or any other relief is appropriate.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Cause of Action)

3. Defendant alleges that the Complaint, and each of its purported causes of action, fails to state facts sufficient to constitute a cause of action against Defendant.

SECOND AFFIRMATIVE DEFENSE

(Due Process Violation)

4. Defendant alleges that the claims asserted and remedies sought by Plaintiff would violate the right of Defendant to due process under the California and United States Constitutions.

THIRD AFFIRMATIVE DEFENSE

(Statutes of Limitations)

5. Defendant alleges Plaintiff's claims are barred in whole or in part by the applicable statute of limitations, California Code of Civil Procedure sections 338(a) and/or 340(a).

FOURTH AFFIRMATIVE DEFENSE

(Lack of Subject Matter Jurisdiction)

6. Defendant alleges that the Court does not have subject matter jurisdiction over the Complaint.

FIFTH AFFIRMATIVE DEFENSE

(Federal Preemption)

7. Defendant alleges that the Complaint, and each claim for relief therein, is barred by the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

(Abstention)

8. Defendant alleges that Plaintiff's claims for relief should be denied under the equitable doctrine of abstention.

SEVENTH AFFIRMATIVE DEFENSE

(No Claim Based on Non-California Conduct)

9. Defendant alleges that Plaintiff's claims are barred in whole or in part to the extent they are based on alleged acts, conduct or statements that were undertaken, made or received outside of California.

EIGHTH AFFIRMATIVE DEFENSE

(Res Judicata/Collateral Estoppel)

10. Defendant alleges that Plaintiff's action is barred by the doctrines of res judicata and/or collateral estoppel.

NINTH AFFIRMATIVE DEFENSE

(Laches)

11. Defendant alleges that Plaintiff is barred by the doctrine of laches from asserting all of the claims in the Complaint.

TENTH AFFIRMATIVE DEFENSE

(Estoppel and Waiver)

12. Defendant alleges that the claims in the Complaint are barred by the doctrines of estoppel and/or waiver.

ELEVENTH AFFIRMATIVE DEFENSE

(Failure to Warn By Third Party)

13. Defendant alleges that the claims in the Complaint are barred to the extent they are based on a failure to provide a warning, as such failure or omission was on the part of persons and entities other than Defendant and said failure or omission was entirely unknown to Defendant.

TWELFTH AFFIRMATIVE DEFENSE

(No Control Over Exposure)

14. Defendant alleges that the exposures of which Plaintiff complains involve acts and omissions of third parties and/or are not within the reasonable ability of this answering Defendant to control.

THIRTEENTH AFFIRMATIVE DEFENSE

(Statutory Exemption)

15. Defendant alleges that pursuant to California Health and Safety Code section 25249.10(c), if there were any exposures to Listed Chemicals as alleged in the Complaint, these would be exempt from the warning requirement of California Health and Safety Code section 25249.6 because, based on evidence and standards of comparable scientific validity as those which form the scientific basis for the listing of the listed chemicals pursuant to California Health and Safety Code section 25249.8(a) and 27 California Code of Regulations section 27001, the alleged exposures have no observable effect of reproductive harm and the alleged exposures pose no significant risk of cancer.

FOURTEENTH AFFIRMATIVE DEFENSE

(Uncertainty)

16. Defendant alleges that the Complaint and each cause of action therein is vague, ambiguous, uncertain and fails to adequately notify Defendant which products are alleged to violate

the Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code section 25249.5, et seq., ("Proposition 65") and which are not alleged to violate Proposition 65.

FIFTEENTH AFFIRMATIVE DEFENSE

(Statutes are Unconstitutional as Applied)

17. Defendant alleges that Plaintiff's claims violate Defendant's rights under the United States and California Constitutions in that, among other things: (1) Plaintiff is attempting to enforce Proposition 65 in a manner that renders the requirements of that statute and regulation unconstitutionally vague; and (2) given the vague, overbroad and uncertain nature of Plaintiff's allegations, requiring Defendant to prove that the alleged exposures cause no significant risk and/or have no observable effect violates Defendant's due process and other constitutional rights.

SIXTEENTH AFFIRMATIVE DEFENSE

(Failure to Join Necessary and/or Indispensable Parties)

18. Defendant alleges that Plaintiff's Complaint fails to name or join all necessary parties pursuant to Code of Civil Procedure sections 389 and 430.10(d).

SEVENTEENTH AFFIRMATIVE DEFENSE

(Naturally Occurring)

19. Defendant alleges that it has not violated California Health and Safety Code § 25249.6 because the listed chemical, the exposure of which Plaintiff alleges constitutes a violation, was naturally occurring, including in water, in the identified Products and, therefore, there is no exposure to such chemical. (California Code of Regulations, Title 27, Section 25501).

EIGHTEENTH AFFIRMATIVE DEFENSE

(First Amendment)

20. Defendant alleges that Plaintiff's Complaint is barred in that Proposition 65 and its implementing regulations to the noticed Products violate Target's right of free speech, in violation of the First Amendment to the United States Constitution, applied to the states by and through the Fourteenth Amendment, and also as guaranteed by the California Constitution, Article I, Section 2(a), as such warnings would be compelled false and misleading speech.

NINETEENTH AFFIRMATIVE DEFENSE

(Reservation of Rights to Assert Additional Defenses)

21. Defendant alleges that it has not knowingly or voluntarily waived any applicable affirmative defenses and reserves the right to assert and rely on such other applicable affirmative defenses as may become available or apparent during discovery proceedings. Defendant further reserves the right to amend its answer and/or affirmative defenses accordingly and/or to declare affirmative defenses that it determines are not applicable during the course of subsequent discovery.

WHEREFORE, Defendant prays for judgment as follows:

A. That Plaintiff takes nothing by reason of the Complaint or any claims stated therein;

B. That the Complaint and each cause of action contained therein be dismissed against Defendant with prejudice;

C. That Defendant recovers its costs, disbursements, expenses, and attorneys' fees herein; and

D. That the Court grant such other and further relief as it may deem just and proper.

Dated: May 26, 2020

NORTON ROSE FULBRIGHT US LLP
JEFFREY B. MARGULIES
LAUREN A. SHOOR
ANDY GUO

By _____
LAUREN SHOOR
Attorneys for Defendant
TARGET CORPORATION

PROOF OF SERVICE

I, Monica Tapia, declare:

I am a citizen of the United States and employed in Los Angeles County, California. I am over the age of eighteen years and not a party to the within-entitled action. My business address is 555 South Flower Street, Forty-First Floor, Los Angeles, California 90071. On May 26, 2020, I served a copy of the within document(s):

DEFENDANT TARGET CORPORATION'S ANSWER TO PLAINTIFF'S COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

☐ by transmitting via facsimile the document(s) listed above to the fax number(s) set forth below on this date before 5:00 p.m.

☐ by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California addressed as set forth below.

☐ by placing the document(s) listed above in a sealed Federal Express envelope and affixing a pre-paid air bill, and causing the envelope to be delivered to a Federal Express agent for delivery.

☐ by personally delivering the document(s) listed above to the person(s) at the address(es) set forth below.

☒ by transmitting via e-mail or other electronic transmission the document(s) listed above to the person(s) at the e-mail address(es) set forth below.

Mark N. Todzo
Joseph Mann
Lexington Law Group
503 Divisadero Street
San Francisco, CA 94117
Tel: (415) 913-7800
Fax: (415) 759-4112
mtodzo@lexlawgroup.com;
jmann@lexlawgroup.com

Attorneys for Plaintiff
Center for Environmental Health

I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on May 26, 2020, at Los Angeles, California.

Monica Tapia

Exhibit 4

LEXINGTON LAW GROUP
Mark N. Todzo (State Bar No. 168389)
Joseph Mann (State Bar No. 207968)
503 Divisadero Street
San Francisco, CA 94117
Telephone: (415) 913-7800
Facsimile: (415) 759-4112
mtodzo@lexlawgroup.com
jmann@lexlawgroup.com

Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et al.*,

Defendants.

Case No. RG 20-054985

FIRST AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

Health & Safety Code § 25249.6, *et seq.*

(Other)

Plaintiff Center for Environmental Health, in the public interest, based on information and belief and investigation of counsel, except for information based on knowledge, hereby makes the following allegations:

INTRODUCTION

1. This Complaint seeks to remedy Defendants' continuing failure to warn individuals in California that they are being exposed to n-nitrosodimethylamine ("NDMA"), a chemical known to the State of California to cause cancer. Such exposures have occurred, and continue to occur, through the manufacture, distribution, sale, and use of over-the-counter acid reducing medications containing ranitidine (the "Products"). Individuals in California are exposed to NDMA when they use the Products.

2. Under California's Proposition 65, Health & Safety Code § 25249.5, *et seq.*, it is unlawful for businesses to knowingly and intentionally expose individuals in California to chemicals known to the State to cause cancer without providing clear and reasonable warnings to such individuals. Defendants introduce Products containing significant quantities of NDMA into the California marketplace, thereby exposing users of their Products to NDMA.

3. Despite the fact that Defendants expose individuals to NDMA, Defendants provide no clear and reasonable warnings about the carcinogenic hazards associated with NDMA exposure. Defendants' conduct thus violates the warning provision of Proposition 65, Health & Safety Code § 25249.6.

PARTIES

4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("CEH") is a non-profit corporation dedicated to protecting the public from environmental health hazards and toxic exposures. CEH is based in Oakland, California and incorporated under the laws of the State of California. CEH is a "person" within the meaning of Health & Safety Code § 25249.11(a) and brings this enforcement action in the public interest pursuant to Health & Safety Code § 25249.7(d). CEH is a nationally recognized non-profit environmental advocacy group that has prosecuted a large number of Proposition 65 cases in the public interest. These cases have resulted in significant public benefit, including the reformulation of thousands of products to

remove toxic chemicals and to make them safer. CEH also provides information to Californians about the health risks associated with exposure to hazardous substances, where manufacturers and other responsible parties fail to do so.

5. Defendant PERRIGO COMPANY is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant PERRIGO COMPANY manufactures, distributes, and/or sells the Products for sale and use in California.

6. Defendant TARGET CORPORATION is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant TARGET CORPORATION manufactures, distributes, and/or sells the Products for sale and use in California.

7. Defendant APOTEX CORP. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant APOTEX CORP. manufactures, distributes, and/or sells the Products for sale and use in California.

8. Defendant GRANULES PHARMACEUTICALS, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant GRANULES PHARMACEUTICALS, INC. manufactures, distributes, and/or sells the Products for sale and use in California.

9. Defendant GRANULES USA, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant GRANULES USA, INC. manufactures, distributes, and/or sells the Products for sale and use in California.

10. Defendant 7-ELEVEN, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant 7-ELEVEN, INC. manufactures, distributes, and/or sells the Products for sale and use in California.

11. DOES 1 through 20 are each a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. DOES 1 through 20 manufacture, distribute, and/or sell the Products for sale and use in California. Defendants PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN, INC.; and DOES 1 through 20 are collectively referred to herein as "Defendants."

12. The true names of DOES 1 through 20 are either unknown to CEH at this time or the applicable time period before which CEH may file a Proposition 65 action has not run. When their identities are ascertained or the applicable time period before which CEH may file a Proposition 65 action has run, the Complaint shall be amended to reflect their true names.

JURISDICTION AND VENUE

13. The Court has jurisdiction over this action pursuant to Health & Safety Code § 25249.7, which allows enforcement in any court of competent jurisdiction, and pursuant to California Constitution Article VI, Section 10, because this case is a cause not given by statute to other trial courts.

14. This Court has jurisdiction over Defendants because each is a business entity that does sufficient business, has sufficient minimum contacts in California, or otherwise intentionally avails itself of the California market through the sale, marketing, or use of the Products in California and/or by having such other contacts with California so as to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

15. Venue is proper in Alameda County Superior Court because one or more of the violations arise in the County of Alameda.

BACKGROUND FACTS

16. The People of the State of California have declared by initiative under Proposition 65 their right "[t]o be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm." Proposition 65, § 1(b).

17. To effectuate this goal, Proposition 65 prohibits exposing people to chemicals listed by the State of California as known to cause cancer, birth defects, or other reproductive harm above certain levels without a "clear and reasonable warning" unless the business responsible for the exposure can prove that it fits within a statutory exemption. Health & Safety Code § 25249.6 states, in pertinent part:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to

> cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . .

18. On October 1, 1987, the State of California officially listed NDMA as a chemical known to cause cancer. 27 Cal. Code Regs. ("C.C.R.") § 27001(b). On October 1, 1988, one year after it was listed as a chemical known to cause cancer, NDMA became subject to the clear and reasonable warning requirement regarding carcinogens under Proposition 65. 27 C.C.R. § 27001(b); Health & Safety Code § 25249.10(b).

19. NDMA is a nitrosamine, a class of chemical compounds that form when nitrates and amino acids combine. NDMA is used in laboratory research to induce tumors in experimental animals. Nitrosamines such as NDMA can also form during the manufacturing process of certain drug products, such as those containing ranitidine.

20. The U.S. Food and Drug Administration ("FDA") performed a root cause analysis to determine how and why nitrosamines, including NDMA, form in ranitidine and other drug products. FDA's analysis determined that NDMA formation can occur in ranitidine through the use of contaminated materials and ingredients, the application of inferior drug manufacturing processes, and improper drug storage after manufacture. Thus, Defendants can reduce or eliminate NDMA from the Products by using cleaner ingredients and manufacturing processes and more careful storage techniques.

21. Defendants' Products contain sufficient quantities of NDMA such that individuals are exposed to NDMA through the average use of the Products. The primary route of exposure is through ingestion when individuals use the Products. These exposures occur everywhere throughout California where the Products are used.

22. No clear and reasonable warning is provided with the Products regarding the carcinogenic hazards of NDMA.

23. The Products are popular over-the-counter medications for treatment of heartburn. They are part of a class of acid reducing products known as H2 blockers, because they block the formation of acid in the stomach. There are a number of other H2 blockers available for over-the-counter sale that do not contain ranitidine. The failure to provide warnings regarding the

carcinogenicity of NDMA in Ranitidine Products is of particular concern in light of evidence that ingestion of NDMA causes cancer and the alternative products on the market that do not contain NDMA.

24. Any person acting in the public interest has standing to enforce violations of Proposition 65 provided that such person has supplied the requisite public enforcers with a valid 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the action within such time. Health & Safety Code § 25249.7(d).

25. More than sixty days prior to naming each Defendant in this lawsuit, CEH provided a 60-Day "Notice of Violation of Proposition 65" to the California Attorney General, to the District Attorneys of every county in California, to the City Attorneys of every California city with a population greater than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code § 25249.7(d) and 27 C.C.R. § 25903(b), each Notice included the following information: (1) the name and address of each violator; (2) the statute violated; (3) the time period during which violations occurred; (4) specific descriptions of the violations, including (a) the routes of exposure to NDMA from the Products, and (b) the specific type of Products sold and used in violation of Proposition 65; and (5) the name of the specific Proposition 65-listed chemical that is the subject of the violations described in each Notice.

26. CEH also sent a Certificate of Merit for each Notice to the California Attorney General, to the District Attorneys of every county in California, to the City Attorneys of every California city with a population greater than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code § 25249.7(d) and 11 C.C.R. § 3101, each Certificate certified that CEH's counsel: (1) has consulted with one or more persons with relevant and appropriate experience or expertise who reviewed facts, studies, or other data regarding the exposures to NDMA alleged in each Notice; and (2) based on the information obtained through such consultations, believes that there is a reasonable and meritorious case for a citizen enforcement action based on the facts alleged in each Notice. In compliance with Health & Safety Code § 25249.7(d) and 11 C.C.R. § 3102, each Certificate served on the Attorney General included factual information – provided on a confidential basis – sufficient to establish the basis

for the Certificate, including the identity of the person(s) consulted by CEH's counsel and the facts, studies, or other data reviewed by such persons.

27. None of the public prosecutors with the authority to prosecute violations of Proposition 65 has commenced and/or is diligently prosecuting a cause of action against Defendants under Health & Safety Code § 25249.5, *et seq.*, based on the claims asserted in each of CEH's Notices.

28. Defendants both know and intend that individuals will use the Products, thus exposing them to NDMA.

29. Under Proposition 65, an exposure is "knowing" where the party responsible for such exposure has:

> knowledge of the fact that a[n] . . . exposure to a chemical listed pursuant to [Health & Safety Code § 25249.8(a)] is occurring. No knowledge that the . . . exposure is unlawful is required.

27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2, § 12601).

30. As companies that manufacture, import, distribute, and/or sell the Products for use in the California marketplace, Defendants know or should know that the Products contain NDMA and that individuals who use the Products will be exposed to NDMA. The NDMA exposures to individuals who use the Products are a natural and foreseeable consequence of Defendants' placing the Products into the stream of commerce.

31. Defendants have also been informed of the NDMA exposures caused by their Products pursuant to the 60-Day Notice of Violation and accompanying Certificate of Merit served on them by CEH.

32. Defendants have also been informed of the NDMA exposures caused by their Products by a series of widely-publicized recalls of Products from the national marketplace due to the presence of NDMA, which commenced in September 2019. These recalls were based on findings of significant quantities of NDMA by an independent laboratory in Products that were already made available for sale to consumers. Following up on these recalls, FDA issued a public

alert that (1) set forth the results of the agency's testing in Products, which also found NDMA in all Products tested, (2) instructed companies selling Products to perform their own testing for NDMA in Products, and (3) advised such companies to recall their Products if testing confirmed the presence of NDMA above certain federal levels.

33. Nevertheless, Defendants continued to expose individuals to NDMA without prior clear and reasonable warnings regarding the carcinogenic hazards of NDMA even after the publicity and recalls.

34. CEH has engaged in good-faith efforts to resolve the claims alleged herein prior to filing this Complaint.

35. Any person "violating or threatening to violate" Proposition 65 may be enjoined in any court of competent jurisdiction. Health & Safety Code § 25249.7. "Threaten to violate" is defined to mean "to create a condition in which there is a substantial probability that a violation will occur." Health & Safety Code § 25249.11(e). Proposition 65 provides for civil penalties not to exceed $2,500 per day for each violation of Proposition 65.

FIRST CAUSE OF ACTION
(Violations of Health & Safety Code § 25249.6)

36. CEH realleges and incorporates by reference as if specifically set forth herein Paragraphs 1 through 35, inclusive.

37. By placing the Products into the stream of commerce, Defendants are each a person in the course of doing business within the meaning of Health & Safety Code § 25249.11.

38. NDMA is a chemical listed by the State of California as known to cause cancer.

39. Defendants know that ordinary use of the Products will expose users of their Products to NDMA. Defendants intend that the Products be used in a manner that results in exposures to NDMA.

40. Defendants have failed, and continue to fail, to provide clear and reasonable warnings regarding the carcinogenicity of NDMA to users of the Products.

41. By committing the acts alleged above, Defendants have at all times relevant to this Complaint violated Proposition 65 by knowingly and intentionally exposing individuals to

NDMA without first giving clear and reasonable warnings to such individuals regarding the carcinogenicity of NDMA.

PRAYER FOR RELIEF

Wherefore, CEH prays for judgment against Defendants as follows:

1. That the Court, pursuant to Health & Safety Code § 25249.7(a), preliminarily and permanently enjoin Defendants from offering Products for sale in California without providing prior clear and reasonable warnings, as CEH shall specify in further application to the Court;

2. That the Court, pursuant to Health & Safety Code § 25249.7(a), order Defendants to take action to stop ongoing unwarned exposures to NDMA resulting from use of Products sold by Defendants, as CEH shall specify in further application to the Court;

3. That the Court, pursuant to Health & Safety Code § 25249.7(b), assess civil penalties against each of the Defendants in the amount of $2,500 per day for each violation of Proposition 65 according to proof;

4. That the Court, pursuant to Code of Civil Procedure § 1021.5 or any other applicable theory, grant CEH its reasonable attorneys' fees and costs of suit; and

5. That the Court grant such other and further relief as may be just and proper.

Dated: November 5, 2020

Respectfully submitted,

LEXINGTON LAW GROUP

Mark N. Todzo
Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

Exhibit 5

LEXINGTON LAW GROUP
Mark N. Todzo (State Bar No. 168389)
Joseph Mann (State Bar No. 207968)
503 Divisadero Street
San Francisco, CA 94117
Telephone: (415) 913-7800
Facsimile: (415) 759-4112
mtodzo@lexlawgroup.com
jmann@lexlawgroup.com

Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et al.*,

Defendants.

Case No. RG 20-054985

SECOND AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

Health & Safety Code § 25249.6, *et seq.*

(Other)

Plaintiff Center for Environmental Health, in the public interest, based on information and belief and investigation of counsel, except for information based on knowledge, hereby makes the following allegations:

INTRODUCTION

1. This Complaint seeks to remedy Defendants' continuing failure to warn individuals in California that they are being exposed to n-nitrosodimethylamine ("NDMA"), a chemical known to the State of California to cause cancer. Such exposures have occurred, and continue to occur, through the manufacture, distribution, sale, and use of over-the-counter acid reducing medications containing ranitidine (the "Products"). Individuals in California are exposed to NDMA when they use the Products.

2. Under California's Proposition 65, Health & Safety Code § 25249.5, *et seq.*, it is unlawful for businesses to knowingly and intentionally expose individuals in California to chemicals known to the State to cause cancer without providing clear and reasonable warnings to such individuals. Defendants introduce Products containing significant quantities of NDMA into the California marketplace, thereby exposing users of their Products to NDMA.

3. Despite the fact that Defendants expose individuals to NDMA, Defendants provide no clear and reasonable warnings about the carcinogenic hazards associated with NDMA exposure. Defendants' conduct thus violates the warning provision of Proposition 65, Health & Safety Code § 25249.6.

PARTIES

4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("CEH") is a non-profit corporation dedicated to protecting the public from environmental health hazards and toxic exposures. CEH is based in Oakland, California and incorporated under the laws of the State of California. CEH is a "person" within the meaning of Health & Safety Code § 25249.11(a) and brings this enforcement action in the public interest pursuant to Health & Safety Code § 25249.7(d). CEH is a nationally recognized non-profit environmental advocacy group that has prosecuted a large number of Proposition 65 cases in the public interest. These cases have resulted in significant public benefit, including the reformulation of thousands of products to

remove toxic chemicals and to make them safer. CEH also provides information to Californians about the health risks associated with exposure to hazardous substances, where manufacturers and other responsible parties fail to do so.

5. Defendant PERRIGO COMPANY is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant PERRIGO COMPANY manufactures, distributes, and/or sells the Products for sale and use in California.

6. Defendant TARGET CORPORATION is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant TARGET CORPORATION manufactures, distributes, and/or sells the Products for sale and use in California. CEH's claims against Defendant TARGET CORPORATION in this action are limited to those Products sold under the Up and Up brand.

7. Defendant APOTEX CORP. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant APOTEX CORP. manufactures, distributes, and/or sells the Products for sale and use in California.

8. Defendant GRANULES PHARMACEUTICALS, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant GRANULES PHARMACEUTICALS, INC. manufactures, distributes, and/or sells the Products for sale and use in California.

9. Defendant GRANULES USA, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant GRANULES USA, INC. manufactures, distributes, and/or sells the Products for sale and use in California.

10. Defendant 7-ELEVEN, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant 7-ELEVEN, INC. manufactures, distributes, and/or sells the Products for sale and use in California.

11. Defendant SANOFI-AVENTIS U.S. LLC is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant SANOFI-AVENTIS U.S. LLC manufactures, distributes, and/or sells the Products for sale and use in California.

12. Defendant CHATTEM INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant CHATTEM INC. manufactures, distributes, and/or sells the Products for sale and use in California.

13. Defendant DR. REDDY'S LABORATORIES LOUISIANA, LLC is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant DR. REDDY'S LABORATORIES LOUISIANA, LLC manufactures, distributes, and/or sells the Products for sale and use in California. CEH's claims against Defendant DR. REDDY'S LABORATORIES LOUISIANA, LLC in this action are limited to those Products sold under the Up and Up brand.

14. Defendant DR. REDDY'S LABORATORIES, INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. Defendant DR. REDDY'S LABORATORIES, INC. manufactures, distributes, and/or sells the Products for sale and use in California. CEH's claims against Defendant DR. REDDY'S LABORATORIES, INC. in this action are limited to those Products sold under the Up and Up brand.

15. DOES 1 through 20 are each a person in the course of doing business within the meaning of Health & Safety Code § 25249.11. DOES 1 through 20 manufacture, distribute, and/or sell the Products for sale and use in California. Defendants PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN, INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC.; and DOES 1 through 20 are collectively referred to herein as "Defendants."

16. The true names of DOES 1 through 20 are either unknown to CEH at this time or the applicable time period before which CEH may file a Proposition 65 action has not run. When their identities are ascertained or the applicable time period before which CEH may file a Proposition 65 action has run, the Complaint shall be amended to reflect their true names.

JURISDICTION AND VENUE

17. The Court has jurisdiction over this action pursuant to Health & Safety Code § 25249.7, which allows enforcement in any court of competent jurisdiction, and pursuant to

California Constitution Article VI, Section 10, because this case is a cause not given by statute to other trial courts.

18. This Court has jurisdiction over Defendants because each is a business entity that does sufficient business, has sufficient minimum contacts in California, or otherwise intentionally avails itself of the California market through the sale, marketing, or use of the Products in California and/or by having such other contacts with California so as to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

19. Venue is proper in Alameda County Superior Court because one or more of the violations arise in the County of Alameda.

BACKGROUND FACTS

20. The People of the State of California have declared by initiative under Proposition 65 their right "[t]o be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm." Proposition 65, § 1(b).

21. To effectuate this goal, Proposition 65 prohibits exposing people to chemicals listed by the State of California as known to cause cancer, birth defects, or other reproductive harm above certain levels without a "clear and reasonable warning" unless the business responsible for the exposure can prove that it fits within a statutory exemption. Health & Safety Code § 25249.6 states, in pertinent part:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . .

22. On October 1, 1987, the State of California officially listed NDMA as a chemical known to cause cancer. 27 Cal. Code Regs. ("C.C.R.") § 27001(b). On October 1, 1988, one year after it was listed as a chemical known to cause cancer, NDMA became subject to the clear and reasonable warning requirement regarding carcinogens under Proposition 65. 27 C.C.R. § 27001(b); Health & Safety Code § 25249.10(b).

23. NDMA is a nitrosamine, a class of chemical compounds that form when nitrates and amino acids combine. NDMA is used in laboratory research to induce tumors in experimental animals. Nitrosamines such as NDMA can also form during the manufacturing process of certain drug products, such as those containing ranitidine.

24. The U.S. Food and Drug Administration ("FDA") performed a root cause analysis to determine how and why nitrosamines, including NDMA, form in ranitidine and other drug products. FDA's analysis determined that NDMA formation can occur in ranitidine through the use of contaminated materials and ingredients, the application of inferior drug manufacturing processes, and improper drug storage after manufacture. Thus, Defendants can reduce or eliminate NDMA from the Products by using cleaner ingredients and manufacturing processes and more careful storage techniques.

25. Defendants' Products contain sufficient quantities of NDMA such that individuals are exposed to NDMA through the average use of the Products. The primary route of exposure is through ingestion when individuals use the Products. These exposures occur everywhere throughout California where the Products are used.

26. No clear and reasonable warning is provided with the Products regarding the carcinogenic hazards of NDMA.

27. The Products are popular over-the-counter medications for treatment of heartburn. They are part of a class of acid reducing products known as H2 blockers, because they block the formation of acid in the stomach. There are a number of other H2 blockers available for over-the-counter sale that do not contain ranitidine. The failure to provide warnings regarding the carcinogenicity of NDMA in Products is of particular concern in light of evidence that ingestion of NDMA causes cancer and the alternative products on the market that do not contain NDMA.

28. Any person acting in the public interest has standing to enforce violations of Proposition 65 provided that such person has supplied the requisite public enforcers with a valid 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the action within such time. Health & Safety Code § 25249.7(d).

29. More than sixty days prior to naming each Defendant in this lawsuit, CEH provided a 60-Day "Notice of Violation of Proposition 65" to the California Attorney General, to the District Attorneys of every county in California, to the City Attorneys of every California city with a population greater than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code § 25249.7(d) and 27 C.C.R. § 25903(b), each Notice included the following information: (1) the name and address of each violator; (2) the statute violated; (3) the time period during which violations occurred; (4) specific descriptions of the violations, including (a) the routes of exposure to NDMA from the Products, and (b) the specific type of Products sold and used in violation of Proposition 65; and (5) the name of the specific Proposition 65-listed chemical that is the subject of the violations described in each Notice.

30. CEH also sent a Certificate of Merit for each Notice to the California Attorney General, to the District Attorneys of every county in California, to the City Attorneys of every California city with a population greater than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code § 25249.7(d) and 11 C.C.R. § 3101, each Certificate certified that CEH's counsel: (1) has consulted with one or more persons with relevant and appropriate experience or expertise who reviewed facts, studies, or other data regarding the exposures to NDMA alleged in each Notice; and (2) based on the information obtained through such consultations, believes that there is a reasonable and meritorious case for a citizen enforcement action based on the facts alleged in each Notice. In compliance with Health & Safety Code § 25249.7(d) and 11 C.C.R. § 3102, each Certificate served on the Attorney General included factual information – provided on a confidential basis – sufficient to establish the basis for the Certificate, including the identity of the person(s) consulted by CEH's counsel and the facts, studies, or other data reviewed by such persons.

31. None of the public prosecutors with the authority to prosecute violations of Proposition 65 has commenced and/or is diligently prosecuting a cause of action against Defendants under Health & Safety Code § 25249.5, *et seq.*, based on the claims asserted in each of CEH's Notices.

32. Defendants both know and intend that individuals will use the Products, thus exposing them to NDMA.

33. Under Proposition 65, an exposure is "knowing" where the party responsible for such exposure has:

> knowledge of the fact that a[n] . . . exposure to a chemical listed pursuant to [Health & Safety Code § 25249.8(a)] is occurring. No knowledge that the . . . exposure is unlawful is required.

27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2, § 12601).

34. As companies that manufacture, import, distribute, and/or sell the Products for use in the California marketplace, Defendants know or should know that the Products contain NDMA and that individuals who use the Products will be exposed to NDMA. The NDMA exposures to individuals who use the Products are a natural and foreseeable consequence of Defendants' placing the Products into the stream of commerce.

35. Defendants have also been informed of the NDMA exposures caused by their Products pursuant to the 60-Day Notice of Violation and accompanying Certificate of Merit served on them by CEH.

36. Defendants have also been informed of the NDMA exposures caused by their Products by a series of widely-publicized recalls of Products from the national marketplace due to the presence of NDMA, which commenced in September 2019. These recalls were based on findings of significant quantities of NDMA by an independent laboratory in Products that were already made available for sale to consumers. Following up on these recalls, FDA issued a public alert that (1) set forth the results of the agency's testing in Products, which also found NDMA in all Products tested, (2) instructed companies selling Products to perform their own testing for NDMA in Products, and (3) advised such companies to recall their Products if testing confirmed the presence of NDMA above certain federal levels.

37. Nevertheless, Defendants continued to expose individuals to NDMA without prior clear and reasonable warnings regarding the carcinogenic hazards of NDMA even after the publicity and recalls.

38. CEH has engaged in good-faith efforts to resolve the claims alleged herein prior to filing this Complaint.

39. Any person "violating or threatening to violate" Proposition 65 may be enjoined in any court of competent jurisdiction. Health & Safety Code § 25249.7. "Threaten to violate" is defined to mean "to create a condition in which there is a substantial probability that a violation will occur." Health & Safety Code § 25249.11(e). Proposition 65 provides for civil penalties not to exceed $2,500 per day for each violation of Proposition 65.

FIRST CAUSE OF ACTION
(Violations of Health & Safety Code § 25249.6)

40. CEH realleges and incorporates by reference as if specifically set forth herein Paragraphs 1 through 39, inclusive.

41. By placing the Products into the stream of commerce, Defendants are each a person in the course of doing business within the meaning of Health & Safety Code § 25249.11.

42. NDMA is a chemical listed by the State of California as known to cause cancer.

43. Defendants know that ordinary use of the Products will expose users of their Products to NDMA. Defendants intend that the Products be used in a manner that results in exposures to NDMA.

44. Defendants have failed, and continue to fail, to provide clear and reasonable warnings regarding the carcinogenicity of NDMA to users of the Products.

45. By committing the acts alleged above, Defendants have at all times relevant to this Complaint violated Proposition 65 by knowingly and intentionally exposing individuals to NDMA without first giving clear and reasonable warnings to such individuals regarding the carcinogenicity of NDMA.

PRAYER FOR RELIEF

Wherefore, CEH prays for judgment against Defendants as follows:

1. That the Court, pursuant to Health & Safety Code § 25249.7(a), preliminarily and permanently enjoin Defendants from offering Products for sale in California without providing prior clear and reasonable warnings, as CEH shall specify in further application to the Court;

2. That the Court, pursuant to Health & Safety Code § 25249.7(a), order Defendants to take action to stop ongoing unwarned exposures to NDMA resulting from use of Products sold by Defendants, as CEH shall specify in further application to the Court;

3. That the Court, pursuant to Health & Safety Code § 25249.7(b), assess civil penalties against each of the Defendants in the amount of $2,500 per day for each violation of Proposition 65 according to proof;

4. That the Court, pursuant to Code of Civil Procedure § 1021.5 or any other applicable theory, grant CEH its reasonable attorneys' fees and costs of suit; and

5. That the Court grant such other and further relief as may be just and proper.

Dated: January 4, 2021

Respectfully submitted,

LEXINGTON LAW GROUP

Mark N. Todzo
Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

Exhibit 6

BLANK ROME LLP
Cheryl S. Chang (SBN 237098)
Chang@BlankRome.com
Erika R. Schulz (SBN 313289)
ESchulz@BlankRome.com
2029 Century Park East, 6th Floor
Los Angeles, CA 90067
Telephone: 424.239.3400
Facsimile: 424.239.3434

Attorneys for Defendant,
APOTEX CORP.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et. al.*,

Defendants.

Case No. RG-20-054985

[*Assigned to Honorable Winifred Y. Smith, Dept. 21*]

DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: April 30, 2021
Time: 10:00
Dept: 21

Complaint Filed: February 19, 2020
SAC Filed: January 4, 2021
Trial Date: None Set

Hearing Reservation ID # R2240282

[*Filed concurrently with Request for Judicial Notice, Declaration of Erika Schulz, and [Proposed] Order*]

NOTICE OF DEMURRER

TO ALL PARTIES AND THEIR ATTORNEY(S) OF RECORD:

PLEASE TAKE NOTICE that on April 30, 2021, at 10:00 a.m., or as soon thereafter as counsel may be heard in Department 21 of the above-entitled Court located at 1221 Oak Street, Oakland, CA 94612, defendant Apotex Corp. ("Apotex") will and hereby does demur ("Demurrer") generally and specially to the second amended complaint ("SAC") filed by plaintiff Center for Environmental Health ("CEH"). Apotex so demurs pursuant to California Code of Civil Procedure Sections 430.10(e) and (f) on the grounds that the SAC fails to allege facts sufficient to constitute any cause of action against it and that CEH's SAC is uncertain, ambiguous and unintelligible.

Pursuant to California Code of Civil Procedure Section 430.41, counsel for Apotex met and conferred with counsel for CEH via telephone on January 20, 2021 and February 2, 2021 in advance of filing the instant Demurrer. The parties were not able reach an agreement resolving Apotex's objections to be raised in this Demurrer. *See* Declaration of Erika Schulz, ¶¶ 4-7.)

Apotex bases the Demurrer upon this Notice, the attached Demurrer, the attached Memorandum of Points and Authorities, the concurrently filed Request for Judicial Notice and exhibits thereto, the Declaration of Erika Schulz, the pleadings, files and records in this action, and such additional matters as may be presented by Apotex at or before the hearing on this Demurrer.

DATED: February 19, 2021

BLANK ROME LLP

By: _____

Cheryl S. Chang
Erika R. Schulz
Attorneys for Defendant,
APOTEX CORP.

DEMURRER

Defendant Apotex Corp. ("Apotex") hereby demurs to the second amended complaint ("SAC") filed by plaintiff Center for Environmental Health ("CEH") on the following grounds:

GENERAL DEMURRER

Apotex demurs to CEH's sole cause of action for violation of Health & Safety Code § 25249.6 *et seq.* ("Proposition 65") asserted in the SAC on the ground that it does not state facts sufficient to constitute a cause of action. (Code Civ. Proc. § 430.10(e).)

FIRST CAUSE OF ACTION

The first and sole cause of action for violation of Proposition 65 fails because it does not state sufficient facts to constitute a cause of action and is uncertain. (Code Civ. Proc. §§ 430.10(e), 430.10(f).)

DATED: February 19, 2021

BLANK ROME LLP

By: _____

Cheryl S. Chang
Erika R. Schulz
Attorneys for Defendant,
APOTEX CORP.

TABLE OF CONETENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

MEMORANDUM OF POINTS AND AUTHORITIES

In support of its demurrer ("Demurrer") to the second amended complaint ("SAC") filed by plaintiff Center for Environmental Health ("CEH"), defendant Apotex Corp. ("Apotex") represents as follows:

I. INTRODUCTION.

CEH's lawsuit against Apotex is a clear abuse of a statute intended to provide a real and substantial benefit to the citizens of California. Months after Apotex withdrew its medication ranitidine from the national market, after its recall received national attention, and after Apotex told FDA that it would no longer market the medication, CEH issued its Notice of Violation under California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). As discussed below, if CEH's action is permitted to proceed, it will provide no public benefit and the only beneficiary will be CEH as it will gain a windfall for pursuing Apotex *after* Apotex took its appropriate and well publicized action. This not only defeats the purpose of private parties suing under Proposition 65 to provide a public benefit, it is the exact type of private plaintiff abuse that California's Attorney General has attempted to limit by recent amendments to the act.

What makes CEH's lawsuit even more troubling is that federal law precluded Apotex from taking any unilateral action to change the label on its ranitidine medication, to change its formulation or even to alter its manner of manufacture. Federal law imposes strict standards on the design, manufacture, and labeling of generic drugs, requiring that the generic version of a drug be the same as the brand. No state law, not even Proposition 65, can require something different. This means, when Apotex's ranitidine was on the market in California, Apotex was powerless to add a Proposition 65 warning to the label, change the formulation of its medication, or alter the manufacturing process because federal law preempts Proposition 65 in this context.

For these reasons, as discussed in more detail below, the Court should sustain Apotex's Demurrer to CEH's SAC, in its entirety, without leave to amend.

II. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND.

Prior to September 25, 2019, Apotex was a supplier of generic ranitidine medications. Request for Judicial Notice ("RJN") ¶¶ 1-3, Exs. 1-3. On September 25, 2019, Apotex

voluntarily issued a nationwide recall of its Products on a precautionary basis due to the potential for detection of NDMA ("Recall"). RJN ¶ 4, Ex. 4. FDA published Apotex's company announcement regarding the Recall the same day. *Id.* Per the Recall, wholesalers, distributors, and retailers were directed to return impacted Apotex Products to their place of purchase. *Id.* Further, anyone with an existing inventory of Apotex Products was directed to quarantine the recalled lots immediately, and customers who purchased the Products directly from Apotex were directed to a point of contact to arrange for their return. *Id.* In addition to publishing the Recall through its company announcement on the FDA website, Apotex "notified its affected direct account Warehousing Chains [to which its Products were distributed] via mail (FedEx Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product." *Id.*

Six months later, on March 27, 2020, CEH issued a Proposition 65 Notice of Violation ("Notice") against Apotex and other entities. RJN ¶¶ 5-6, Exs. 5-6. The Notice asserts violations of Proposition 65 based on alleged exposure to the chemical n-nitrosodimethylamine ("NDMA") in over-the-counter ("OTC") acid-reducing medications containing ranitidine ("Products") without the requisite warning. *Id.*

To enforce its claims alleged in the Notice, CEH filed its original complaint ("Complaint") and commenced this action on February 19, 2020. The Complaint named only two defendants: Perrigo Company and Target Corporation. On November 6, 2020, CEH filed its first amended complaint ("FAC") naming additional defendants, including Apotex. On January 4, 2021, CEH filed the operative SAC, which added four more defendants to the action. The operative complaint asserts a single cause of action for violation of Proposition 65. *See generally, SAC.* CEH seeks relief in the form of injunctive relief, civil penalties, and attorneys' fees. *Id.*

III. DEMURRER STANDARD.

A demurrer challenges defects that appear on the face of the complaint. *Blank v. Kirwan* (1985) 39 Cal.3d 311, 318. A defendant may demur on the ground that the complaint does not

state facts sufficient to constitute a cause of action or on the grounds that the allegations are uncertain, ambiguous, and unintelligible. Cal. Code Civ. Proc. §§ 430.10(e)-(f).

Even under today's liberal pleading standard, a plaintiff must nevertheless "set forth in his complaint the essential facts of his case with reasonable precision and with sufficient clarity and particularity, so that the defendant may be apprised of the nature, source and extent of the cause of action." *Metzenbaum v. Metzenbaum* (1948) 86 Cal.App.2d 750, 753. Courts "do not, however, assume the truth of 'mere contentions or assertions contradicted by judicially noticeable facts.'" *Debrunner v. Deutsche Bank Nat. Trust Co.* (2012) 204 Cal.App.4th 433, 439 (quoting *Kirwan*, 39 Cal.3d at 318). Accordingly, "[d]oubt in the complaint may be resolved against plaintiff and facts not alleged are presumed not to exist." *Kramer v. Intuit Inc.* (2004) 121 Cal.App.4th 574, 578. In ruling on a demurrer, "in addition to the facts actually pleaded, the court considers facts of which it may or must take judicial notice." *Rodas v. Spiegel* (2001) 87 Cal.App.4th 513, 517 (2001), *as modified* (Feb. 28, 2001).

Finally, "federal preemption presents a pure question of law" and is "properly handled by demurrer." *Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1089 n.10, citing *Spielholz v. Superior Court* (2001) 86 Cal.App.4th 1366, 1371; *Washington Mut. Bank v. Superior Court* (2002) 95 Cal.App.4th 606, 612, *as modified* (Feb. 15, 2002).

IV. ARGUMENT.

A. CEH's "Enforcement" Action Following a Nationwide Recall of the Products Is Moot, Including Because There Are No Grounds for Injunctive Relief and No Public Benefit From Its Action to Warrant an Award of Attorneys' Fees.

1. Proposition 65 Is Fundamentally an Equitable Statute.

Proposition 65, codified at Cal. Health & Safety Code § 25249.6 *et seq.*, provides in relevant part: "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual," subject to certain exceptions. A private party may bring an action "in the public interest" if the Attorney General has not commenced the case and 60 days after giving notice of violation, including a certification that "there is a reasonable and meritorious case for the private action." *Id.* at § 25249.7(d). At

its core, it is a "right to know" statute and a "remedial law, designed to protect the public." *Ctr. for Self-Improvement & Cmty. Dev. v. Lennar Corp.* (2009) 173 Cal.App.4th 1543, 1550–51.

Proposition 65 is "fundamentally equitable" in both its "purpose and remedy: to facilitate the *notification* of the public of potentially harmful substances, so informed decisions may be made by consumers on the basis of disclosure." *DiPirro v. Bondo Corp.* (2007) 153 Cal.App 4th 150, 183, *as modified* (Aug. 8, 2007) (emphasis in original). Consistent with Proposition 65's equitable purpose, "[a]n award of civil penalties under the Act is a statutory punitive exaction ***determined on the basis of equitable principles, designed to deter misconduct and harm***, not to compensate the plaintiff for actual damages sustained." *Id.* (emphasis added). "[T]he statutory remedies afforded by the Act, including civil penalties, are not damages at law, but instead constitute ***equitable relief appropriate as incidental to enforcement of the Act***," and in that capacity "do not entitle [a Proposition 65] plaintiff to a jury trial." *Id.* at 184 (emphasis added).

Under Proposition 65, "if there is no evidence of threat, but only the abstract possibility of violation, no injunction may issue." *Consumer Cause, Inc. v. Johnson & Johnson* (2005) 132 Cal. App. 4th 1175, 1186 (Proposition 65 was intended only to protect against known or threatened hazards, not hypothetical or speculative ones). Further, "[m]ethods of warning should be crafted when warnings are needed, based on a[n] 'actual set of facts,' and not in the abstract. Moreover, they should be crafted by the parties who have something at stake." *Id.* at 1184, citing *Pac. Legal Found. v. California Coastal Com.* (1983) 33 Cal.3d 158, 170.

In light of this statutory background and purpose, CEH's enforcement action has no merit for the reasons set forth below.

2. Apotex's Voluntarily Issued Recall of Its Ranitidine Products in September 2019 Preceded CEH's Notice By Over Half a Year.

Apotex's Recall predated CEH's March 27, 2020 Notice by six months. The Recall also predated CEH's FAC, through which Apotex was first added to the action, by just over one year, and predated the operative SAC by over one year and three months. Further, through its Recall, Apotex went above and beyond mere cessation of sales in California, the only state in which Proposition 65 applies. Instead, it voluntarily recalled its Products on a nationwide basis in coordination with FDA. RJN ¶ 4, Ex. 4. By ceasing sales and issuing its Recall on a nationwide

basis to all channels of commerce, Apotex took additional measures to ensure that no out-of-state Products later crossed into California through interstate commerce, a risk inherent in a California-only recall scheme based on the limited reach of Proposition 65. In addition, Apotex has notified FDA that it has discontinued both of its OTC formulations of ranitidine, indicating an intention to not return to the market. RJN ¶¶ 1-3 & 7, Exs. 1-3 & 7.

3. FDA Subsequently Requested Removal of All Ranitidine Products from the Market in April 2020.

On April 1, 2020, months after Apotex's voluntary Recall and shortly after CEH's Notice, FDA publicly requested the immediate removal of all ranitidine products—prescription and over-the-counter—from the market. RJN ¶ 8, Ex. 8. Per the FDA News Release, "As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S." *Id.* This sweeping request for immediate market removal predated CEH's FAC[1] by approximately seven months and predated the SAC by over nine months.

With its April 1 announcement, FDA also sent letters to all manufacturers of ranitidine requesting that they withdraw their products from the market, although Apotex had already done so through its voluntary recall half a year earlier. RJN ¶ 9, Ex. 9. FDA further advised consumers taking OTC ranitidine products to stop taking them, to dispose of them, and to not buy more. RJN ¶ 8, Ex. 8. FDA's News Release further confirms that FDA is conducting a thorough investigation of NDMA content in ranitidine medications, and that it "continues its ongoing review, surveillance, compliance, and pharmaceutical quality efforts across every product area, and will continue to work with drug manufacturers to ensure safe, effective, and high-quality drugs for the American public." *Id.*

4. CEH's Claim for Injunctive Relief Is Moot and Improper in Light of Apotex's and FDA's Removal of Ranitidine from the Nationwide Market.

CEH has no basis to seek injunctive relief against Apotex because the Apotex-manufactured Products were recalled from the market six months prior to the Notice, and over

[1] As noted above, Apotex was first added to this action through the FAC and was not a party to the original Complaint.

one year before Apotex was added to this lawsuit. "Injunctive relief is appropriate only when there is a threat of continuing misconduct." *Madrid v. Perot Sys. Corp.* (2005) 130 Cal.App.4th 440, 463. A change in circumstances or facts rendering injunctive relief moot or unnecessary justifies denial of the request for such relief. *Scripps Health v. Marin* (1999) 72 Cal.App.4th 324, 332. Moreover, "not only can injunctive relief be denied where the defendant has voluntarily discontinued the wrongful conduct," but "there exists no equitable reason for ordering it where the defendant has in good faith discontinued the [allegedly] proscribed conduct."[2] *Id.* at 332-333.

Here, despite the fact that Apotex Covered Products were voluntarily cleared from the market on a nationwide basis in September 2019, CEH nonetheless proceeded with this baseless enforcement action seeking to "enjoin [Apotex] from offering Products for sale in California without providing prior clear and reasonable warnings," and "to stop ongoing unwanted exposures to NDMA resulting from the use of Products sold [and since recalled] by [Apotex]." *See* SAC, Prayer for Relief. The relief sought is wholly illusory: the Apotex-manufactured Products have not been on the market since well before CEH's enforcement efforts and Apotex has discontinued both of its OTC ranitidine products indicating its intention to not return to the market. Even if Apotex had not undertaken its voluntary recall in 2019, FDA's subsequent request for removal of all ranitidine products from the market moots any claim for injunctive relief by CEH relating to *any* Products—whether manufactured or supplied by Apotex or not. Finally, both Apotex and FDA directed consumers to return or dispose of any Products in their possession, mooting any injunctive relief claims relating to possible exposures from the long-recalled Products. RJN ¶¶ 4 & 8, Exs. 4 & 8.

Likewise, this Court should not entertain CEH's claim for injunctive relief based on any unsubstantiated conjecture that, notwithstanding the product recalls which CEH itself recognizes,[3] at some point in the future a defendant *may* decide to sell a product and that the manufacturer's label *could* possibly violate Proposition 65, or that the FDA may or may not take

[2] Apotex maintains that the conduct at issue is not "proscribed," including due to the application of federal preemption as discussed herein.

[3] *See* SAC ¶ 36.

certain action in the future. "An injunction properly issues only where the right to be protected is clear, injury is impending and so immediately likely as only to be avoided by issuance of the injunction." *E. Bay Mun. Util. Dist. v. Dep't of Forestry & Fire Prot.* (1996), 43 Cal.App 4th 1113, 1126; *see also, Connerly v. Schwarzenegger* (2007) 146 Cal.App.4th 739, 750 ("[I]njunctions cannot be predicated on the proponent's fear of something that may happen in the future."); *Korean Philadelphia Presbyterian Church v. California Presbytery* (2000) 77 Cal.App.4th 1069, 1084, *as modified* (Feb. 9, 2000) (same).

Here, Apotex provided to FDA notification that it had withdrawn its OTC ranitidine Products from the market and that they are no longer available for sale, causing FDA to classify Apotex's OTC ranitidine Products as "discontinued." RJN ¶ 1-3 & 7, Exs. 1-3 & 7. Apotex cannot unilaterally return its ranitidine Products to the market in California—or anywhere else—without prior FDA approval. RJN ¶ 9, Ex. 9. Further, FDA's Information Request to Apotex and every other manufacturer of ranitidine states:

> The Agency will not approve any pending supplement until FDA finds appropriate controls have been implemented and stability data submitted demonstrating adequate control of drug quality, specifically NDMA. To reintroduce your product to the market, submit a supplemental application with the results of your analysis of the cause(s) and extent of NMDA formation, proposed changes to manufacturing process or other controls, and at least 12 months stability data; 3 months of accelerated stability data; and months 1, 2, and 3 and the 12 month (or midpoint) in-use stability data per the table above.

Id. Any injunctive relief here would not only be unripe for judicial determination, it would be contingent upon and bridled to the results of FDA's own NDMA management plan and would only amount to unwarranted private "gatekeeping" by CEH under the premise of Proposition 65 enforcement.

The injunctive relief sought here is thus illusory, baseless, and improper. All ranitidine Products have been withdrawn from the market by FDA for an unspecified period of time, with FDA setting a high threshold for market reentry. Apotex has not articulated an intention to re-enter the drug market with ranitidine and cannot do so without FDA approval. Neither CEH nor Apotex can predict what that FDA approval process might entail, including whether FDA will set an acceptable level of NDMA, prescribe a new federal warning, or withdraw market approval for the product entirely. In light of these uncertainties, CEH's future enforcement plans are

hypothetical and highly contingent at best, and certainly do not meet the stringent requirements for injunctive relief.

Without a legitimate basis for injunctive relief, Apotex's voluntary remedial action long prior to CEH's enforcement attempts, and FDA's regulatory activity specifically aimed at this very issue, CEH's Proposition 65 claim fails on its face.

5. Because Apotex's Voluntary Recall Was Unrelated and Prior to CEH's Proposition 65 Enforcement Efforts, CEH Does Not Meet Qualify as a "Successful Party" and Is Not Entitled to an Award of Attorneys' Fees.

In its SAC, CEH seeks attorneys' fees and costs of suit resulting from its enforcement action pursuant to Code of Civil Procedure § 1021.5, the private attorney general doctrine.[4] The California Attorney General's Proposition 65 settlement guidelines, codified at Cal. Code Regs. tit. 11, § 3200 *et seq.*, are instructive regarding the application of the private attorney general doctrine in a Proposition 65 context, including the requirements to justify an award of attorneys' fees. Critically, in its analysis of the requirements to justify an award of attorneys' fees in this context, the regulations also outline the requirements for a Proposition 65 enforcer to be considered a "successful party." Specifically, the guidelines explain that the private attorney general doctrine permits an award of attorneys' fees to a "successful party . . . in any action which has resulted in the enforcement of an important right affecting the public interest if: (a) a significant benefit . . . has been conferred on the general public or a large class of persons, (b) the necessity and financial burden of private enforcement . . . are such as to make the award appropriate, and (c) such fees should not in the interest of justice be paid out of the recovery, if any." Cal. Code Regs. tit. 11, § 3201, Cal. Civ. Proc. Code § 1021.5. The guidelines go on to explain when those "successful party" requirements are met. Here, CEH has failed to demonstrate the necessity of its private enforcement and has failed to confer any public benefit from its misguided and redundant enforcement efforts.

[4] In addition to Code of Civil Procedure § 1021.5, as a catch-all, CEH also notes in its SAC that it seeks fees pursuant to "any other applicable theory." However, Apotex is unaware of any other theory pursuant to which an award of attorneys' fees would be justified or appropriate in this context. *See, e.g.*, Cal. Code Regs. tit. 11, § 3201.

First, Cal. Code Regs., tit. 11, § 3201, subd. (c) provides: "To establish necessity of private enforcement, the plaintiff should establish that its continued prosecution of the action was necessary to obtain the relief in the settlement."[5] Further, Cal. Code Regs., tit. 11, § 3201, subd. (a) holds that the plaintiff's action must be the "catalyst" for the defendant's change in conduct in order for the plaintiff to be deemed "successful." Here, Apotex's withdrawal of its ranitidine Products from the market long preceded CEH's enforcement efforts, including CEH's Notice and this lawsuit. The sweeping market withdrawal was a result of Apotex's voluntary recall, reinforced by FDA's subsequent request for immediate removal of all ranitidine products from the market. The removal of the products from the nationwide market meant that, by the time CEH issued its notice and filed suit against Apotex to "enforce" Proposition 65, Apotex had already come into compliance with Proposition 65 by ceasing sales to California consumers (and to consumers nationwide), and by directing consumers to return or dispose of any existing stock of the product, thereby halting any potential regulated exposures without the requisite warning. *See* Cal. Health & Safety Code § 25249.6 (Proposition 65 proscribes the "knowing[] and intentional[]" exposure of individuals to regulated chemicals without first providing a clear and reasonable warning, subject to certain exceptions.) As a result, CEH cannot demonstrate that its private enforcement here was necessary, that its continued prosecution of this action was or is necessary to obtain the relief it seeks, or that its action was the "catalyst" for Apotex's change in conduct (*i.e.*, the recall).

In addition, Cal. Code Regs., tit. 11, § 3201, subd. (b) explains when an enforcer can be deemed to have conferred a "public benefit" sufficient for the enforcer to be considered a "successful party" under the private attorney general doctrine. That section states: "If there is no evidence of an exposure for which a warning plausibly is required, there is no significant public benefit, even if a warning is given." Cal. Code Regs. tit. 11, § 3201(b)(1). Here, Apotex undertook a sweeping voluntary recall that predated CEH's earliest enforcement efforts against Apotex. The recall included a direction for wholesalers, distributors, retailers, and consumers to

[5] As noted above, these regulations are framed as settlement guidelines. Although this case is not in settlement posture, these settlement guidelines are nonetheless instructive in assessing the merits of a Proposition 65 case, including whether a party can be classified as a "successful party" under the parameters of the private attorney general doctrine.

return Apotex Products. Through these actions, Apotex effectuated compliance with Proposition 65 by ceasing sales to California, seeking returns of existing inventory, and eliminating potential exposures requiring warnings that could have resulted from the Apotex Products. CEH's action long after such compliance cannot be deemed to have conferred any public benefit with respect to Apotex Products.

Further, with respect to conferring a public benefit via reformulation, "the mere agreement to a reformulation standard or formula may not establish the existence of a public benefit." Cal. Code Regs. tit. 11, § 3201(b)(2). Here, CEH's proposed enforcement action does not (and cannot) confer a greater public benefit than FDA's threshold for drug manufacturers to reenter the ranitidine market by requiring an analysis of the causes and extent of NDMA formation, proposed changes to manufacturing process or other controls, and detailed stability data. *See* Section IV.A.3, *supra.*, and RJN ¶ 9, Ex. 9.

Accordingly, CEH cannot be considered a "successful party" here. An award of attorneys' fees is not justified, and the SAC seeking to "remedy Defendants' continuing failure to warn" should be dismissed due to the redundancy and frivolousness of the relief "in the public interest" that it purports to seek. SAC ¶ 1.

6. Civil Penalties Are Not Warranted.

As set forth in Section IV.A.1 above, Proposition 65 is inherently an equitable statute, and civil penalties are merely incidental to its ***equitable*** enforcement. *DiPirro*, 153 Cal.App 4th at 183-184. For this reason alone, civil penalties are not warranted here, because there is no basis for the required equitable or injunctive relief as set forth above. *See also, Communities for a Better Env't v. Tosco Corp.*, No. 300595, 2002 WL 1916051, at *1 (Cal. Super. Ct. Aug. 8, 2002) (unpublished) (even though civil penalties were available under Proposition 65, Proposition 65 plaintiff's action was equitable in nature, as penalties were merely a tool for enhancing accomplishment of predominant purpose of Proposition 65, to protect consumers by invoking equitable remedies to stop alleged violations).

Further, the chronology of Apotex's voluntary Recall half a year prior to CEH's Notice demonstrates that CEH's lawsuit is an attempt to collect a windfall under Prop 65 where its

private attorney general actions can confer no benefit on the public and are based solely and improperly in hypothetical or speculative hazards. *See Consumer Cause, Inc.*, 132 Cal. App. 4th at 1186. CEH is asking this Court to give *it* credit for Apotex's self-initiated Recall despite CEH having no involvement and only coming on the scene months later. The Attorney General's Settlement Guidelines confirm there are situations in which it may be "entirely appropriate" not to impose any penalty. Cal. Code Regs. tit. 11, § 3203(a) (a settlement with no penalty may be entirely appropriate based on the facts or circumstances of a particular case).[6] Such is the case here. A penalty would be improper where Apotex took early, independent, and sweeping good faith measures to comply by removing its Products from the market six months before CEH issued its pre-lawsuit Notice. Cal. Health & Safety Code § 25249.7(b)(2)(D)-(E) (in assessing the amount of a civil penalty under Proposition 65, the Court shall consider "[w]hether the [alleged] violator took good faith measures to comply with this chapter and the time those measures were taken," as well as the "willfulness" of the alleged violator's misconduct.)

A penalty here is likewise improper where it will have no deterrent effect on Apotex or any other company involved in the sale or manufacture of ranitidine Products, since FDA has indefinitely requested removal of the products from the market on a nationwide basis pending its own stringent control and approval procedures discussed above. Any potential deterrent effect of an after-the-fact state law penalty is superseded and extinguished by FDA's prior market removal of the Products and ongoing gatekeeping. Indeed, the lack of deterrent effect is especially clear where Apotex undertook its own voluntary compliance measures early-on, even before FDA's actions. *See* Cal. Health & Safety Code § 25249.7(b)(2)(F) (in assessing the amount of a civil penalty under Proposition 65, the Court shall consider "[t]he deterrent effect that the imposition of the penalty would have on both the violator and the regulated community as a whole.")

Rather, allowing CEH to proceed would have the perverse effect of deterring the kind of early and well publicized action that Apotex here undertook to remove its ranitidine from the

[6] Apotex acknowledges that this provision is part of the Attorney General's settlement guidelines and that it is framed accordingly. However, Apotex cites the provision here to demonstrate that the Attorney General has determined that penalties need not be assessed or applied in every case where a violation is alleged.

market upon first notice that it may contain a dangerous substance. CEH acknowledges that Apotex's recall was "widely-publicized", but misleadingly fails to attribute the recall to Apotex. SAC ¶ 36. Now, Apotex stands to be whipsawed for taking precisely the kind of action Proposition 65 encourages. Accordingly, in addition to there being no basis for injunctive relief or attorneys' fees, there is also no basis for imposition of a civil penalty here, and CEH's Proposition 65 claim against Apotex should be dismissed in its entirety.

B. CEH'S Claims Are Federally Preempted Under Theories of Conflict Preemption (Impossibility) and Field Preemption.

Under the Supremacy Clause of the United States Constitution, "the Laws of the United States... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. The preemption doctrine derives from the Supremacy Clause. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n* (1992) 505 U.S. 88, 108.

There are three circumstances in which state law is preempted under Supremacy Clause. First, under express preemption, "Congress can define explicitly the extent to which its enactments pre-empt state law." *English v. Gen. Elec. Co.* (1990) 496 U.S. 72, 78. Second, under conflict preemption, "state law is pre-empted to the extent that it actually conflicts with federal law." *Id.* at 79. Within conflict preemption, a subset of impossibility preemption exists "where it is impossible for a private party to comply with both state and federal requirements." *Id.* Third, under field preemption, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.*

Consistent with these principles, the Proposition 65 regulations provide that Proposition 65 "shall not apply to any of the following: ... An exposure for which federal law governs warning in a manner that preempts state authority." Cal. Health & Safety Code § 25249.10. As discussed further below, CEH's state-law Proposition 65 claims are federally preempted under the theories of conflict preemption and field preemption. Accordingly, its SAC should be dismissed.

1. Plaintiff's Proposition 65 Claims are Preempted Based on Conflict Preemption/Impossibility Because the FDCA Prohibits Generic Drug Manufacturers from Unilaterally Changing the Design or Formulation of a Generic Medicine, Altering Its FDA-Approved Labeling, or Issuing Additional Warnings.

Under the theory of conflict preemption, "state laws that require a private party to violate a federal law are pre-empted and, thus, are without effect." *Mut. Pharm. Co. v. Bartlett* (2013) 570 U.S. 472, 475, citing *Maryland v. Louisiana* (1981) 451 U.S. 725, 728 (internal quotations omitted). Further, "[a] holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." *Fla. Lime & Avocado Growers, Inc. v. Paul* (1963) 373 U.S. 132, 142–43.

CEH's SAC defines the Products at issue as "over-the-counter acid reducing medications containing ranitidine". SAC ¶ 1. The OTC Products manufactured by Apotex are generic, not brand-name. RJN ¶¶ 1-3, Exs. 1-3. Proposition 65 is preempted with respect to generic drugs, as compliance with the requirements of Proposition 65 would implicate—and impossibly conflict with—federal law governing the labeling,[7] formulation, and manufacture of generic drugs. The United States Supreme Court decisions in *Mensing* and *Bartlett* are dispositive on this issue. In addition, a recent opinion issued by the U.S. District Court for the Southern District of Florida in the multidistrict litigation titled *In re: Zantac (Ranitidine) Products Liability Litigation* granted the generic drug manufacturers' motion to dismiss (which included claims against Apotex) based on the very same preemption arguments raised here. Each is discussed in turn below.

a. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, manufactures of generic drugs argued that it would be impossible for them to comply with state law requirements mandating heightened warnings ***and***

[7] FDA defines "labeling" as "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the ''Physicians Desk Reference'') for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act." 21 C.F.R. §202.1(l)(2)

federal law, because FDA regulations "required them to use the same the same safety and efficacy labeling as their brand-name counterparts." *PLIVA, Inc. v. Mensing* (2011) 564 U.S. at 610. The Court confirmed that "brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label... A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 613, citing 21 U.S.C. §§ 355(b)(1), (d); §§ 355(j)(2)(A)(v); §§ 355(j)(4)(g); 21 C.F.R. §§ 314.94(a)(8); §§ 314.127(a)(7); *Wyeth v. Levine* (2009) 555 U.S. 555, 570-71. The Court went on to explain that FDA "require[s] that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" *Mensing*, 564 U.S. at 613. The Court found that conflict preemption applied, holding:

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them... Taking [plaintiffs-respondents'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels... Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same.

Id. at 618. The Court also noted that the question for "impossibility" is "whether the private party could ***independently*** do under federal law what state law requires of it." *Id.* at 620 (emphasis added).

Here, the only Products at issue with respect to Apotex are generic OTC ranitidine medications. RJN ¶¶ 1-3, Exs. 1-3. Thus, as in *Mensing*, it would be impossible for Apotex to comply with Proposition 65's warning requirement independently without running afoul of the federal laws governing generic drug warning labels.

b. *Mut. Pharm. Co. v. Bartlett*

In *Bartlett*, the Supreme Court reaffirmed and expanded upon the preemption principles set forth in *Mensing*. Like in *Mensing*, the Court held that "it was impossible for [a manufacturer of a generic drug] to comply with both its state-law duty to strengthen the warnings on [the generic drug]'s label and its federal-law duty not to alter [the generic drug]'s label. Accordingly,

the state law is pre-empted." *Mut. Pharm. Co. v. Bartlett* (2013) 570 U.S. 472, 480. The Court did not stop its conflict analysis there. The Court also analyzed obstacles with respect to product reformulation. Specifically:

> [R]edesign for reformulation of the generic drug] was not possible for two reasons. First, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based... Consequently, the Court of Appeals was correct to recognize that '[the manufacturer] cannot legally make [the generic drug at issue] in another composition.' Indeed, were Mutual to change the composition of its [generic drug], the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce.

Id. at 483-84. Accordingly, the Court confirmed that reformulation (or redesign) was likewise an "impossibility." *Id* at 84. The same is true here: the generic drug at issue cannot legally be reformulated lest it run afoul of the FDCA's requirements for generic drug formulation, dosage form, and strength, resulting in impossibility.

After finding state-law warning and reformulation requirements preempted with respect to generic drugs, the *Bartlett* Court finally turned to the Court of Appeals' reasoning that the manufacturer "could escape the impossibility of complying with both its federal- and state-law duties" by choosing not to make the generic drug at all, or by withdrawing from the market entirely. *Id.* at 488. The Supreme Court summarily rejected this "stop-selling" proposition "as incompatible with our pre-emption jurisprudence." *Id.* In short, the mere fact that a manufacturer could stop selling the product does not defeat an impossibility conflict. *Id.* at 489, citing *Mensing*, 131 S. Ct. at 2578. To hold otherwise would mean that "the vast majority—if not all—of the cases in which the Court has found impossibility-preemption, were wrongly decided." *Bartlett*, 570 U.S. at 489.

Similarly, due to the constraints upon generic manufacturers under federal law, Apotex cannot legally reformulate its drug in order to comply with state law here. In addition, requiring Apotex to simply "stop selling" its Products in order to comply with state law is not a viable solution to the preemption conflict.

Together, *Bartlett* and *Mensing* confirm that, even if Apotex did manufacture the ranitidine Products at issue or was somehow responsible for the application of Proposition 65 warnings, it could not have provided a warning or reformulated the product at any time relevant

to CEH's claims—nor could Apotex reformulate or provide a warning at any foreseeable time in the future. Likewise, the Supreme Court has confirmed that requiring cessation of sales in light of such conflict is simply not an option. Because compliance with both federal regulations and Proposition 65 is a physical and practical impossibility here—whether compliance with Proposition 65 is enforced through warning, reformulation, or cessation of sales— Proposition 65 is preempted as it relates to Apotex's generic Products. Because CEH's underlying claims are preempted, CEH has no basis to pursue relief for any existing violations, let alone for the speculative and highly contingent future violations that it hypothesizes may occur.

c. *In re: Zantac (Ranitidine) Products Liability Litigation Order Granting Generic Manufacturers' and Repackagers' Motion to Dismiss on the Grounds of Preemption*

On December 31, 2020, the U.S. District Court for the Southern District of Florida granted a motion to dismiss brought by manufacturers of generic ranitidine products (including Apotex) on the basis of federal preemption. RJN ¶ 10, Ex. 10. This order ("MDL Order") considered the very same Products and alleged chemical content at issue in this case and relied upon the very same Supreme Court authorities discussed above.

In relevant part, the MDL Order addressed plaintiffs' slew of state law claims relating to misbranding, design defect, and failure to warn against generic drug manufacturers based on NDMA content in ranitidine medication.[8] The MDL Order confirmed that "[t]he design-defect and failure-to-warn claims that the Supreme Court ruled in *Mensing* and *Bartlett* are pre-empted as against generic drug manufacturers are pre-empted as against Defendants, regardless of Plaintiffs' allegations that ranitidine products were misbranded…" *Id.* It thus held that "Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are dismissed with prejudice as pre-empted." *Id.* Likewise:

> "[A] claim based on an allegation that a generic drug's formulation renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved [. . .] Thus, Plaintiffs' claims based on alleged defects in ranitidine products, product labeling, or other communications that Generic Manufacturer Defendants could not

[8] The only federal claims against the generic manufacturer defendants were for violations of the Magnuson Moss Warranty Act, which requires a valid state-law warranty claim. RJN ¶ 10, Ex. 10.

> independently change while remaining in compliance with federal law are pre-empted. This includes, but is not limited to, claims based on allegations that ranitidine products were defectively designed because they break down into NDMA and claims based on failure to warn consumers that the products contained NDMA or could break down into NDMA when ingested."

Id. The Court ruled that "Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are **DISMISSED WITH PREJUDICE** consistent with this order." *Id.*

In both the multidistrict litigation and this case, Apotex faces (or faced) claims that its generic drug failed to provide adequate warnings under state law, and/or claims that its product violated state law due to its composition or design. CEH itself concedes the same. *See, e.g.*, SAC ¶ 1 ("This Complaint seeks to remedy Defendants' continuing **failure to warn** individuals in California…") (emphasis added), ¶ 2 ("Defendants introduce Products containing significant quantities of NDMA into the California marketplace, thereby exposing users of their Products to NDMA."), ¶ 44 (characterizing the cause of action as follows: "Defendants have failed, and continue to fail, to provide clear and reasonable warnings regarding the carcinogenicity of NDMA to users of the Products.") Therefore, the same result is compelled here, and CEH's claims must be dismissed as against Apotex.

CEH's claims are inherently failure-to-warn claims, but Apotex anticipates that CEH may attempt to reframe its claims as something else to avoid preemption. Instead of admitting that its claims relate to warnings, labeling, or product composition or design, CEH may rely on a single sentence in its SAC to save its doomed claims. CEH alleges that "Defendants can reduce or eliminate NDMA from the Products by using cleaner ingredients and manufacturing processes and more careful storage techniques." SAC ¶ 24. But the MDL Order dismissed claims that "ranitidine products were defectively designed because they break down into NDMA." RJN ¶ 10, Ex. 10. The MDL Court found, as have dozens of other courts, allegations based on changing ranitidine's ingredients – changing its design – are preempted. Thus, this Court must likewise dismiss CEH's claims as preempted.[9]

[9] Notably, plaintiffs in the MDL abandoned their manufacturing defect claims when filing their Amended Master Personal Injury Complaint, suggesting such claims have no merit.

Federal regulations also preclude Apotex from unilaterally altering how it manufactures or stores ranitidine. When a plaintiff claims that state law requires a change and under federal law and the change is defined as a "major change" under FDA regulations, the state-law claim is preempted. *See, e.g., Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9-10 (1st Cir. 2018). The implementing regulation for the statutory "major change" requirement, 21 C.F.R. § 314.70(b), has a two-part structure. The regulation provides in section (b)(1) that changes that have "a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product" are "major changes" requiring FDA approval. But the regulation ***also*** provides in section (b)(2) "a host of ensuing categories of changes to drug products, listed at sections (b)(2)(i) through (viii)," all of which FDA has ***pre-determined*** are "major changes." *Gustavsen*, 903 F.3d at 10 (concluding that "if a change fits under any of the categories listed in section (b)(2), that change necessarily constitutes a 'major' change requiring FDA pre-approval"). To that end, 21 C.F.R. § 314.70(b)(2) states that "major changes" include:

> Changes in the synthesis or manufacture of the drug substance that may affect the *impurity profile* and/or the *physical, chemical, or biological properties* of the drug substance.

21 C.F.R. § 314.70(b)(2)(iv).

CEH's fundamental theory of liability is that Apotex's ranitidine Products violated California state law by exposing consumers to NDMA without the requisite warning on the drug's label and that the NDMA may have been a result of the manufacturing process. But to have implemented the kind of changes in its manufacturing process CEH suggests (SAC ¶ 24), Apotex would have to obtain prior FDA approval because even changes directed toward removing one impurity could adversely affect the impurity profile of the medication with respect to other impurities, or impact the physical, chemical or biological properties of the drug substance. Whether CEH's allegations regarding manufacturing processes are changes that "may affect the impurity profile" or are aimed at an alleged "physical, chemical, or biological propert[y]" of ranitidine, they are "major changes" that require FDA pre-approval under 21 C.F.R. § 314.70(b)(2)(iv) and (vi). Consequently, the Court must dismiss CEH's SAC as preempted. *See Gustavsen*, 903 F.3d at 9-11.

But even if Apotex could have unilaterally changed its manufacturing process, any such reimagined claim by CEH still could not overcome the application of preemption here based on the language of the Proposition 65 regulations themselves. Specifically, Cal. Health & Safety Code § 25249.10 specifically states that "Section 25249.6 [Proposition 65] shall not apply to any of the following: (a) An exposure for which federal law ***governs warning*** in a manner that preempts state authority." (emphasis added). Here, federal law does in fact govern ***warning*** in a manner that preempts state authority: generic drugs cannot provide warnings that differ from their brand-name counterparts under federal law, as discussed at length above. It does not matter whether claims relating to "cleaner ingredients," "manufacturing processes," or "more careful storage techniques" are preempted or not. Because federal law governs ***warning*** in a manner that preempts state authority with respect to Apotex's Products, Proposition 65 expressly does not apply.

Regardless of CEH's tangential allegations about other ways to eliminate NDMA from the Products besides reformulation (or besides complying through warnings), its claims against Apotex are still preempted and should be dismissed with prejudice. CEH has no way to replead its claims to overcome the fact that federal law governs warning with respect to generic drugs in a manner that preempts the conflicting requirements under Proposition 65.

2. FDA's Comprehensive Investigation, Oversight, and Management of Potential NDMA Content in Ranitidine Products Supports the Application of Field Preemption.

State law is preempted under the theory of field preemption where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. *English*, 496 U.S. at 78. Such congressional intent may be inferred from "a scheme of federal regulation... so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Rice v. Santa Fe Elevator Corp.* (1948) 331 U.S. 218, 230. Significantly, "[w]hen Congress occupies an entire field... ***even complementary state regulation is impermissible***. Field preemption reflects a congressional decision to foreclose any state

regulation in the area, even if it is parallel to federal standard." *Arizona v. United States* (2012) 567 U.S. 387, 401.

To be clear, Apotex recognizes that the mere fact of ***general*** federal regulation of drugs under the federal FDCA ***alone*** is not sufficient to preempt state law claims on a field preemption basis. *See, e.g., Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 924 (Congress "did not occupy the field of labeling of over-the counter drugs."); *Jackson v. Perry Drug Stores, Inc.*, No. 195680, 1997 WL 33330749, at *1 (Mich. Ct. App. Dec. 9, 1997) (rejecting argument that Federal Food, Drug and Cosmetic Act occupies the entire field of drug labeling regulation).

However, the question of field preemption here is ***not*** limited to whether Congress intended to occupy the field of labeling, formulation, and manufacture of California OTC drugs through its enactment of the FDCA and/or through the FDCA's attendant implementing regulations, which apply to all drugs. Here, there is a unique situation in which FDA has taken affirmative and drastic steps to control and regulate the sale, marketing, manufacture, stability, and testing of ranitidine drugs ***specifically***—and with respect to NDMA content in particular—beyond the mandates of the FDCA's general drug regulations. RJN ¶¶ 8-9, Exs. 8-9. FDA's robust oversight and management of potential NDMA in ranitidine products supports a finding of field preemption, as confirmed by FDA's own statements and actions, including its nationwide recall and investigation of the controls and quality management of manufacturers. *Id.*

In *R.F. v. Abbott Labs.*, a blood transfusion recipient brought state law products liability claims for failure to warn against a manufacturer of an early, commercially available HIV blood screening test. *R.F. v. Abbott Labs.* (2000) 162 N.J. 596. The test was used to test blood at the blood bank for HIV, but was unsuccessful in the plaintiff's case, and she tested positive for HIV after receiving a blood transfusion. *Id.* at 599. Plaintiff claimed that the blood test used was defective because the package insert failed to provide adequate instructions or warnings regarding the sensitivity limitations allegedly inherent in the manufacturer's test. *Id.* at 599-600.

The Court found that plaintiff's claims were impliedly[10] preempted by FDA's unique regulation of the test. *Id.* at 620. Namely, FDA's exercise of control and initiative over the test's development, packaging, and field performance monitoring, and the unique circumstances under which the test arose (the national health crisis concerning the AIDS epidemic and the loss of a safe blood supply) gave rise to implied preemption. *Id.* In reaching this conclusion, the court observed that, among other oversights and controls, FDA engaged in a "whole host of monitoring efforts" over the test, and that the manufacturer tested a portion of every manufactured lot by FDA order. *Id.* at 611-12. Further, and as is the case here, the Court observed that the manufacturer's product license "specifically prohibited it from unilaterally altering the Test's package insert or disseminating additional warnings through 'Dear Doctor' letters or otherwise." *Id.* at 621.

The *Abbott* Court ruled that "the extensive control and continuous scrutiny of the Test by the FDA was so pervasive as to make reasonable the inference that [the FDA] left no room for the state[s] to supplement it." *Id.* at 625 (internal quotations omitted). "The FDA's active involvement at every step of the test's development, approval, and use in the field, reflected the risk-utility analysis undertaken by the FDA to address significant public policy considerations." *Id.* at 626. In reaching its preemption conclusion based on the "unique facts" of FDA's robust involvement in and oversight of the test, the court clarified: "This is not a case where a

[10] The Court admits that the categories of preemption are muddled: "the Supreme Court and leading constitutional scholars agree that preemption categories are not 'rigidly distinct.'" *Abbott Labs.*, 162 N.J. at 618, citing *Gade v. Nat'l Solid Wastes Management Assoc.* (1992) 505 U.S. 88, 103 n.2 (internal quotations omitted). However, as the dissent makes clear, "[t]he Court's preemption discussion relies most heavily on the doctrine of 'field' preemption." *Id.* at 646 (Stein, J., dissenting). In characterizing the preemption at issue here as "field preemption," Apotex is simply following the three categories of preemption described in *English,* 496 U.S. 72, which the *Abbott* court recharacterizes as express preemption, conflict preemption, and "implied preemption" (rather than "field preemption"). *Id.* at 618. The *Abbott* Court goes on to say that "implied preemption" includes the subsets of field preemption, conflict preemption, and obstacle preemption. *Id.* at 620. In any case, by using the name "field preemption" here, Apotex ***does not*** intend to foreclose, waive, or limit any application of federal preemption it asserts elsewhere, whether described more broadly as "implied" preemption or as "field" preemption. Apotex does not intend for its nomenclature to limit this Court' application of preemption.

manufacturer is shielding itself from a claim by use of the general mandates of the FDA." *Id.* at 629, 637.

Similarly, field preemption here is not based on the mere general fact that FDA regulates all drugs, OTC drugs, and/or generic drugs through the FDCA or its implementing regulations. Instead, through its unique actions described above, FDA has comprehensively and completely stepped into the field regarding NDMA content in OTC ranitidine drugs specifically, leaving no room for state law to regulate.

FDA's News Release confirms that FDA is taking aggressive, severe, and comprehensive action at multiple levels to address the issue of NDMA in ranitidine medications, including issuing an immediate nationwide request for removal of the Products from the market, directly contacting all manufacturers to request withdrawal, and advising consumers to dispose of their existing Product stock and to cease buying more. RJN ¶¶ 8-9, Exs. 8-9. Further, FDA's News Release confirms that it is conducting a thorough investigation of NDMA content in ranitidine medications, and is undertaking ongoing review, surveillance, compliance, and pharmaceutical quality efforts. RJN ¶ 8, Ex. 8. Even more, in its Information Request to Apotex, FDA confirms in detail (1) that it will be responsible for "find[ing] adequate a supplemental application that demonstrates adequate control over NDMA" in the Products; (2) that manufacturers must submit to FDA their market withdrawal plans and timelines; (3) that FDA sets the stability requirements and specific studies required in order for a manufacturer to gain approval of a pending application or FDA concurrence to resume distribution of the Products; (4) that FDA "will not approve any pending supplement until FDA finds appropriate controls have been implemented and stability data submitted demonstrating adequate control of drug quality, specifically NDMA"; (5) that FDA will review manufacturers' "proposed changes to manufacturing process and other controls" before allowing reintroduction of the Products to the market, among other controls. RJN ¶ 9, Ex. 9. In brief, FDA's oversight is nothing short of exhaustive.

FDA's comprehensive investigation, intervention, recall, and setting of quality control and manufacturing standards with respect to this specific medication and the potential contamination issue commands a finding of field preemption here. CEH cannot step on FDA's

toes through its effort to enforce state law claims where FDA has elbowed it out. This is true ***even if*** CEH contends that its state law claims are "complementary" or "parallel to" the federal standards. *Arizona*, 567 U.S. at 401.

Accordingly, this Court should dismiss CEH's SAC without leave to amend, as CEH will be unable to amend or plead around the fact of FDA's complete occupation of the very field which CEH's state law claims seek to concurrently occupy. This is true whether CEH frames the issue as one of labeling, failure to warn, reformulation, manufacturing, quality control, storage, stability, or testing: regardless of the nature of the relief sought or alleged violation, the over-arching field at issue—NDMA content in OTC ranitidine medications—remains wholly and unavoidably occupied by FDA.

V. CONCLUSION.

Based upon the foregoing, Apotex respectfully requests that its Demurrer to CEH's SAC be sustained, in its entirety, without leave to amend.

DATED: February 19, 2021

BLANK ROME LLP

By: _____

Cheryl S. Chang
Erika R. Schulz
Attorneys for Defendant,
APOTEX CORP.

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is **BLANK ROME LLP**, 2029 Century Park East, 6th Floor, Los Angeles, California 90067.

On **February 19, 2021**, I served the foregoing document(s): DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF on the interested parties in this action addressed and sent as follows:

SEE ATTACHED SERVICE LIST

☒ **BY ENVELOPE:** by placing ☐ the original ☒ a true copy thereof enclosed in sealed envelope(s) addressed as indicated and delivering such envelope(s):

☒ **BY MAIL:** I caused such envelope(s) to be deposited in the mail at Los Angeles, California with postage thereon fully prepaid to the office or home of the addressee(s) as indicated. I am "readily familiar" with this firm's practice of collection and processing documents for mailing. It is deposited with the U.S. Postal Service on that same day, with postage fully prepaid, in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in affidavit.

☐ **BY FEDEX:** I caused such envelope(s) to be deposited in a box or other facility regularly maintained by FedEx, an express service carrier, or delivered to a courier or driver authorized by said express service carrier to receive documents in an envelope designated by the said express service carrier, addressed as indicated, with delivery fees paid or provided for, to be transmitted by FedEx.

☒ **BY ELECTRONIC SERVICE (EMAIL):** Pursuant to Temporary Emergency Rule #12 related to electronic service of documents via email enacted by the California Judicial Counsel due to the National Emergency and public health orders in California related to the coronavirus and COVID-19 pandemic, I caused the document(s) listed above to be transmitted to the person(s) at the e-mail address(es) as indicated. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the transmission was incomplete or unsuccessful.

☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on **February 19, 2021**, at Los Angeles, California.

Michelle Grams

SERVICE LIST

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Mark N. Todzo Joseph Mann LEXINGTON LAW GROUP 503 Divisadero Street San Francisco, CA 94117 Telephone: (415) 913-7800 Facsimile: (415) 759-4112 Email: mtodzo@lexlawgroup.com; jmann@lexlawgroup.com;	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Dennis Raglin Danielle Vallone STEPTOE & JOHNSON LLP 633 West Fifth St., Suite 1900 Los Angeles, CA 90071 Email: draglin@steptoe.com; dvallone@steptoe.com	Attorneys for Defendant PERRIGO COMPANY
Jeffrey B. Margulies Lauren A. Shoor Andy Guo NORTON ROSE FULBRIGHT US LLP 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Telephone: (213) 892-9200 Facsimile: (213) 892-9494 Email: jeff.margulies@nortonrosefulbright.com; lauren.shoor@nortonrosefulbright.com; andy.guo@nortonrosefulbright.com	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers LEWIS BRISBOIS BISGAARD & SMITH LLP 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: (415) 438-6615 Fax: (415) 434-0882 Email: Paul.desrochers@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.
Walter (Pete) H. Swayze, III Megan E. Grossman LEWIS BRISBOIS BISGAARD & SMITH LLP Philadelphia, PA 550 E. Swedesford Road, Suite 270 Wayne, PA 19087 Tel: (215) 977-4100 Fax: (215) 977-4101 Email: Pete.Swayze@lewisbrisbois.com; Megan.Grossman@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Brian Ledger GORDON REESE SCULLY MANSUKHANI LLP 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: (619) 696-6700 Fax: (619) 696-7124 Email: bledger@gordonrees.com	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas Greg Sperla DLA PIPER 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: (916) 930-3200 Fax: (916) 930-3201 Email: George.gigounas@dlapiper.com; Greg.sperla@dlapiper.com	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner Deepi K. Miller GREENBERG TRAURIG, LLP 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: (916) 442-1111 Fax: (916) 448-1709 Email: wagnerw@gtlaw.com; millerde@gtlaw.com	Attorneys for Defendant 7-ELEVEN, INC.
Trenton H. Norris ARNOLD & PORTER KAYE SCHOLER LLP 10th Floor Three Embarcadero Center San Francisco, CA 94111-4024 Tel: (415) 471-3100 Fax: (415) 471-3400 Email: Trent.Norris@arnoldporter.com	
Linda E. Maichl John R. Ipsaro Megan B. Gramke ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202-2409 Tel: (513) 698-5000 Fax: (513) 698-5013 Email: lmaichl@ulmer.com; jipsaro@ulmer.com; mgramke@ulmer.com	Attorneys for Defendants DR. REDDY'S LABORATORIES LOUISIANA, LLC and DR. REDDY'S LABORATORIES, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Richard M. Barnes
Sean Gugerty
GOODELL, DEVRIES, LEECH & DANN, LLP
One South Street, 20th Floor
Baltimore, MD 21202
Tel: 410-783-4000
Fax: 410-783-4040
Email: rmb@gdldlaw.com;
sgugerty@gdldlaw.com

Attorneys for Defendant
PERRIGO COMPANY

Exhibit 7

BLANK ROME LLP
Cheryl S. Chang (SBN 237098)
Chang@BlankRome.com
Erika R. Schulz (SBN 313289)
ESchulz@BlankRome.com
2029 Century Park East, 6th Floor
Los Angeles, CA 90067
Telephone: 424.239.3400
Facsimile: 424.239.3434

Attorneys for Defendant,
APOTEX CORP.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et. al.*,

Defendants.

Case No. RG-20-054985

[*Assigned to Honorable Winifred Y. Smith, Dept. 21*]

DECLARATION OF ERIKA SCHULZ RE: GOOD FAITH ATTEMPT TO MEET AND CONFER PURSUANT TO CODE OF CIVIL PROCEDURE § 430.41(a)(2)

Date: April 30, 2021
Time: 10:00 a.m.
Dept: 21

Complaint Filed: February 19, 2020
SAC Filed: January 4, 2021
Trial Date: None Set

Hearing Reservation ID #R2240282

[*Filed concurrently with Demurrer, Request for Judicial Notice, and [Proposed] Order*]

DECLARATION OF ERIKA SCHULZ

I, Erika Schulz, do declare as follows:

1. I am a member of the Bar of the State of California and an associate in the law firm of Blank Rome LLP, attorneys for defendant Apotex Corp. ("Apotex") in the above-referenced action. I make this declaration pursuant to Code of Civil Procedure Section 430.41(a)(2) in support of Apotex's Demurrer ("Demurrer") to the Second Amended Complaint ("SAC") filed by plaintiff Center for Environmental Health ("CEH"). I have personal knowledge of the facts set forth in this declaration, and if called upon to testify as a witness, I could and would competently testify to the following facts.

2. CEH filed its operative SAC on January 4, 2021. The parties initially had a discrepancy in their respective calculations of SAC response deadlines in light of their differing interpretations regarding service of the SAC. For avoidance of doubt, the parties agreed that Apotex's deadline to respond to the complaint would be February 15, 2021.

3. The parties later agreed by stipulation on or about February 10, 2021 that Apotex's deadline to respond to the SAC would be further extended to February 19, 2021, consistent with the proposed joint briefing schedule applicable to all defendants in this matter. On February 18, 2021, the Court clerk emailed counsel for the parties in this matter reservation confirmations for the defendants' respective demurrers for April 30, 2021.

4. My office and CEH's counsel communicated on several occasions by letter, email, and telephone to discuss the bases and authorities for Apotex's anticipated Demurrer.

5. For example, on January 20, 2021 at approximately noon PST, I met and conferred with CEH's counsel Joe Mann to discuss Apotex's Demurrer to the SAC. I was accompanied on the call by Terry Henry, a partner at my firm. During the call, we discussed the various grounds for the Demurrer, including Apotex's position that CEH's enforcement action following a nationwide recall of the subject product(s) is moot, including in that it provides no grounds for injunctive relief, no public benefit, and no basis for attorneys' fees. We also discussed Apotex's position that, because it is a generic manufacturer, CEH's claims against it are federally preempted under theories of conflict (impossibility) preemption and field

preemption. The parties exchanged information and authorities in support of their respective positions.

6. On February 2, 2021 at approximately 4:00 p.m. PST, I met and conferred with CEH's counsel again, accompanied by Terry Henry and Cheryl Chang, partners at my firm. The parties followed up regarding their respective positions on the arguments to be raised in the Demurrer, including in light of the authorities and information exchanged after the January 20 meet and confer call.

7. As of the date of filing of this declaration, and despite our good-faith effort to meet and confer to resolve our disputed issues, the parties have been unable to reach an agreement resolving the objections to be raised in Apotex's Demurrer.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 19th day of February, 2021, at Los Angeles, California.

Erika Schulz

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is **BLANK ROME LLP**, 2029 Century Park East, 6th Floor, Los Angeles, California 90067.

On **February 19, 2021**, I served the foregoing document(s): DECLARATION OF ERIKA SCHULZ RE: GOOD FAITH ATTEMPT TO MEET AND CONFER PURSUANT TO CODE OF CIVIL PROCEDURE § 430.41(a)(2) on the interested parties in this action addressed and sent as follows:

SEE ATTACHED SERVICE LIST

☒ **BY ENVELOPE:** by placing ☐ the original ☒ a true copy thereof enclosed in sealed envelope(s) addressed as indicated and delivering such envelope(s):

☒ **BY MAIL:** I caused such envelope(s) to be deposited in the mail at Los Angeles, California with postage thereon fully prepaid to the office or home of the addressee(s) as indicated. I am "readily familiar" with this firm's practice of collection and processing documents for mailing. It is deposited with the U.S. Postal Service on that same day, with postage fully prepaid, in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in affidavit.

☐ **BY FEDEX:** I caused such envelope(s) to be deposited in a box or other facility regularly maintained by FedEx, an express service carrier, or delivered to a courier or driver authorized by said express service carrier to receive documents in an envelope designated by the said express service carrier, addressed as indicated, with delivery fees paid or provided for, to be transmitted by FedEx.

☒ **BY ELECTRONIC SERVICE (EMAIL):** Pursuant to Temporary Emergency Rule #12 related to electronic service of documents via email enacted by the California Judicial Counsel due to the National Emergency and public health orders in California related to the coronavirus and COVID-19 pandemic, I caused the document(s) listed above to be transmitted to the person(s) at the e-mail address(es) as indicated. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the transmission was incomplete or unsuccessful.

☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on **February 19, 2021**, at Los Angeles, California.

Michelle Grams

SERVICE LIST

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Mark N. Todzo Joseph Mann LEXINGTON LAW GROUP 503 Divisadero Street San Francisco, CA 94117 Telephone: (415) 913-7800 Facsimile: (415) 759-4112 Email: mtodzo@lexlawgroup.com; jmann@lexlawgroup.com;	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Dennis Raglin Danielle Vallone STEPTOE & JOHNSON LLP 633 West Fifth St., Suite 1900 Los Angeles, CA 90071 Email: draglin@steptoe.com; dvallone@steptoe.com	Attorneys for Defendant PERRIGO COMPANY
Jeffrey B. Margulies Lauren A. Shoor Andy Guo NORTON ROSE FULBRIGHT US LLP 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Telephone: (213) 892-9200 Facsimile: (213) 892-9494 Email: jeff.margulies@nortonrosefulbright.com; lauren.shoor@nortonrosefulbright.com; andy.guo@nortonrosefulbright.com	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers LEWIS BRISBOIS BISGAARD & SMITH LLP 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: (415) 438-6615 Fax: (415) 434-0882 Email: Paul.desrochers@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.
Walter (Pete) H. Swayze, III Megan E. Grossman LEWIS BRISBOIS BISGAARD & SMITH LLP Philadelphia, PA 550 E. Swedesford Road, Suite 270 Wayne, PA 19087 Tel: (215) 977-4100 Fax: (215) 977-4101 Email: Pete.Swayze@lewisbrisbois.com; Megan.Grossman@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Brian Ledger GORDON REESE SCULLY MANSUKHANI LLP 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: (619) 696-6700 Fax: (619) 696-7124 Email: bledger@gordonrees.com	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas Greg Sperla DLA PIPER 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: (916) 930-3200 Fax: (916) 930-3201 Email: George.gigounas@dlapiper.com; Greg.sperla@dlapiper.com	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner Deepi K. Miller GREENBERG TRAURIG, LLP 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: (916) 442-1111 Fax: (916) 448-1709 Email: wagnerw@gtlaw.com; millerde@gtlaw.com	Attorneys for Defendant 7-ELEVEN, INC.
Trenton H. Norris ARNOLD & PORTER KAYE SCHOLER LLP 10th Floor Three Embarcadero Center San Francisco, CA 94111-4024 Tel: (415) 471-3100 Fax: (415) 471-3400 Email: Trent.Norris@arnoldporter.com	
Linda E. Maichl John R. Ipsaro Megan B. Gramke ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202-2409 Tel: (513) 698-5000 Fax: (513) 698-5013 Email: lmaichl@ulmer.com; jipsaro@ulmer.com; mgramke@ulmer.com	Attorneys for Defendants DR. REDDY'S LABORATORIES LOUISIANA, LLC and DR. REDDY'S LABORATORIES, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Richard M. Barnes
Sean Gugerty
GOODELL, DEVRIES, LEECH & DANN, LLP
One South Street, 20th Floor
Baltimore, MD 21202
Tel: 410-783-4000
Fax: 410-783-4040
Email: rmb@gdldlaw.com;
sgugerty@gdldlaw.com

Attorneys for Defendant
PERRIGO COMPANY

Exhibit 8

BLANK ROME LLP
Cheryl S. Chang (SBN 237098)
Chang@BlankRome.com
Erika R. Schulz (SBN 313289)
ESchulz@BlankRome.com
2029 Century Park East, 6th Floor
Los Angeles, CA 90067
Telephone: 424.239.3400
Facsimile: 424.239.3434

Attorneys for Defendant,
APOTEX CORP.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et. al.*,

Defendants.

Case No. RG-20-054985

[*Assigned to Honorable Winifred Y. Smith, Dept. 21*]

DEFENDANT APOTEX CORP.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF ITS DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Date: April 30, 2021
Time: 10:00 a.m.
Dept: 21

Complaint Filed: February 19, 2020
SAC Filed: January 4, 2021
Trial Date: None Set

Hearing Reservation ID #R2240282

[*Filed concurrently with Demurrer, Declaration of Erika Schulz, and [Proposed] Order*]

TO ALL PARTIES AND TO THEIR RESPECTIVE ATTORNEYS OF RECORD:

Pursuant to California Code of Civil Procedure § 430.30(a), California Evidence Code §§ 452 and 453 and Rule 3.1306 of the California Rules of Court, defendant Apotex Corp. ("Apotex") hereby requests the Court to take judicial notice of the following documents which are not reasonably subject to dispute and are capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy:

1. Publicly-available search results for all drugs by applicant "Apotex" with search term "Ranitidine" obtained from the United States Food and Drug Administration ("FDA") website for FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), available at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm?panel=1&applicant=Apotex (accessed February 16, 2021). A true and correct copy of the subject FDA Orange Book search results is attached hereto as **Exhibit 1**. Product details for each of the three non-prescription/non-RX (and since discontinued) ranitidine drugs by applicant Apotex appearing in this search are provided below in ¶¶ 2-4, Exs. 2-4.

2. Publicly available Product Details for "ANDA 075167," Ranitidine Hydrochloride (Ranitidine Hydrochlride) EQ 75MG BASE obtained from FDA's website for FDA's Orange Book, available at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=075167#9319 (accessed February 16, 2021). A true and correct copy of the Orange Book Product Details for ANDA 075167 is attached hereto as **Exhibit 2.**

3. Publicly available Product Details for "ANDA 200172," Ranitidine Hydrochloride (Ranitidine Hydrochlride) EQ 150MG BASE obtained from FDA's website for FDA's Orange Book, available at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=200172#16328 (accessed February 16, 2021). A true and correct copy of the Orange Book Product Details for ANDA 200172 is attached hereto as **Exhibit 3.**

4. The September 25, 2019 Company Announcement titled, "Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All pack sizes and

Formats) due to the potential for Detection of an Amount of Unexpected Impurity,N-nitrosodimethylamine (NDMA) Impurity in the Product," obtained from FDA's website under the "Safety" section and "Recalls, Market Withdrawals, & Safety Alerts" subsection, available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and#:~:text=Apotex%20Corp.,Issues%20Voluntary%20Nationwide%20Recall%20of%20Ranitidine%20Tablets%2075mg%20and%20150mg,NDMA)%20Impurity%20in%20the%20product (accessed February 16, 2021). A true and correct copy of FDA's posting of the September 25, 2019 Company Announcement is attached hereto as **Exhibit 4.**

5. The State of California Department of Justice, Office of the Attorney General ("OAG")'s publicly available website listing for the Proposition 65 60-Day Notice dated March 27, 2020, AG Number 2020-00822 ("Notice") issued by plaintiff Center for Environmental Health ("CEH") to Apotex, Granules USA, Inc., and Granules Pharmaceuticals, Inc., regarding N-Nitrosodimethylamine (NDMA) in "OTC Ranitidine Products." The OAG's website listing for CEH's Notice is available at https://oag.ca.gov/prop65/60-Day-Notice-2020-00822 (accessed February 16, 2021), and includes information about the complaints associated with the Notice filed in this Court and in this case, including "Case Name: CEH v. Perrigo Company, et al," "Court Name: Alameda County Superior Court," and "Court Docket Number: RG 20-054985." A true and correct copy of the OAG's website listing for CEH's Notice is attached hereto as **Exhibit 5.**

6. CEH's March 27, 2020 Proposition 65 Notice to Apotex, Granules USA, Inc., and Granules Pharmaceuticals, Inc. as provided on the OAG's publicly available website referenced in ¶ 5, Ex. 5 above, available at https://oag.ca.gov/system/files/prop65/notices/2020-00822.pdf (accessed February 16, 2021). A true and correct copy of CEH's Notice is attached hereto as **Exhibit 6.**

7. The August 2020 publication by the U.S. Department of Health and Human Services, FDA, Center for Drug Evaluation and Research (CDER) titled "Marketing Status Notifications Under Section 5061 of the Federal Food, Drug, and Cosmetic Act; Content and

Format Guidance for Industry," publicly available on FDA's website at https://www.fda.gov/media/120095/download (accessed February 16, 2021). A true and correct copy of the August 2020 CDER publication is attached hereto as **Exhibit 7.**

8. The April 1, 2020 FDA News Release titled, "FDA Requests Removal of All Ranitidine Products (Zantac) from the Market," obtained from FDA's website under "Press Announcements," available at https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market (accessed February 16, 2021). A true and correct copy of FDA's April 1, 2020 News Release is attached hereto as **Exhibit 8.**

9. FDA's Information Request letters to Apotex in reference to Apotex's abbreviated new drug application (ANDA) for Ranitidine Tablets USP, 75mg, ANDA 075167 and 150mg, ANDA 200172, signed by Michael Kopcha and Donald D. Ashley on March 31, 2020. True and correct copies of FDA's Information Request letters are attached hereto as **Exhibit 9.**

10. The December 31, 2020 Order Granting Generic Manufactuers' [*sic*] and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption in the matter titled *In Re: Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924, 20-MD-2924, in the United States District Court for the Southern District of Florida. A true and correct conformed copy of the December 31, 2020 Order is attached hereto as **Exhibit 10.**

This request for judicial notice ("Request") is made on the grounds that the Court may take judicial notice of information that cannot reasonably be controverted, even if it negates an express allegation of the pleading. *Columbia Casualty Co. v. Northwestern Nat. Ins. Co.* (1991) 231 Cal.App.3d 457, 468-69. Accordingly, judicially noticeable facts may supersede any inconsistent factual allegations contained in a complaint. *Del E. Webb Corp. v. Structural Materials Co.* (1981) 123 Cal.App.3d 593, 604.

Pursuant to Evidence Code section 452(h), the court may take judicial notice of "[f]acts and propositions that are not reasonably subject to dispute and are capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy." Section 452(c) of the Evidence Code further provides that the court may take judicial notice of "official acts" of the state and federal legislative, executive, and judicial departments. Such "official acts" include

"records, reports, and orders of administrative agencies." *See Rodas v. Spiegel*, 87 Cal. App. 4th 513, 518 (2001). In addition, pursuant to California Evidence Code section 452(b), judicial notice may be taken of "regulations and legislative enactments issued by or under the authority of the United States or any public entity in the United States."

Consistent with these principles, California courts have routinely granted judicial notice of documents, correspondence, rulings, and informal agency decisions of federal regulatory agencies such as FDA, including where such documents made available on official government websites. *Tamas v. Safeway, Inc.* (2015) 235 Cal.App.4th 294, 297–98 ("In support of its demurrer, [defendant] asked the court to take judicial notice of various federal regulations, FDA rulings contained in the federal register, and a memorandum summarizing questions and answers from a 2004 'Regional Milk Seminar, an Advanced Milk Processing Course and a Special Problems in Milk Protection Course' available on the FDA Web site. The court granted that request in its entirety."); *People ex rel. Lockyer v. Tri-Union Seafoods, LLC*, No. CGC-01-420975, 2006 WL 1544377, at *2 (Cal. Super. Ct. May 12, 2006) (unpublished) (taking judicial notice of letter from FDA Commissioner to Attorney General of California, reasoning that the FDA opinion letter "amounts to informal agency decision and should be given proper deference"); *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal. 4th 910, 922, fn. 4 (taking judicial notice of FDA letter to plaintiff addressing pregnancy warnings accompanying nicotine replacement therapy products); *Smiley v. Citibank* (1995) 11 Cal.4th 138, 145, fn. 2, *aff'd sub nom. Smiley v. Citibank (S. Dakota), N.A.* (1996) 517 U.S. 735 (taking judicial notice of "certain documents from the Office of the Comptroller of the Currency and other federal administrative agencies"); *Bell v. Farmers Ins. Exch.* (2004) 115 Cal.App.4th 715, 735, *as modified on denial of reh'g* (Mar. 9, 2004) (taking notice of various United States Department of Labor opinion letters).

In addition, it is appropriate for courts to take judicial notice of an official publication of a state's Attorney General's office. *People v. Crusilla* (1999) 77 Cal. App. 4th 141, 147.

/ / /

/ / /

Finally, this Court is expressly authorized to take judicial notice of the records of any court of this state or any court of the United States. *See* Cal. Evid. Code § 452(d).

DATED: February 19, 2021

BLANK ROME LLP

By: _____
Cheryl S. Chang
Erika R. Schulz
Attorneys for Defendant,
APOTEX CORP.

EXHIBIT 1

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Modify Search (index.cfm?panel=1&applicant=Apotex)

Search Results for Applicant: *Apotex*

RX OTC DISCN

CSV Excel Print

Display 50 records per page

Showing 1 to 5 of 5 entries (filtered from 522 total records)

Ranitidine

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/u
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074680 (results_product.cfm?Appl_Type=A&Appl_No=074680#23357)	TABLET	ORAL	EQ 150MG BASE	AB
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074680 (results_product.cfm?Appl_Type=A&Appl_No=074680#23358)	TABLET	ORAL	EQ 300MG BASE	AB
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077602 (results_product.cfm?Appl_Type=A&Appl_No=077602#11126)	SYRUP	ORAL	EQ 15MG BASE/ML	
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075167 (results_product.cfm?Appl_Type=A&Appl_No=075167#9319)	TABLET	ORAL	EQ 75MG BASE	
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A200172 (results_product.cfm?Appl_Type=A&Appl_No=200172#16328)	TABLET	ORAL	EQ 150MG BASE	
Mkt. Status	**Active Ingredient**	**Proprietary Name**	**Appl. No.**	**Dosage Form**	**Route**	**Strength**	**TE Code (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/u**

Showing 1 to 5 of 5 entries (filtered from 522 total records)

Previous 1 Next

EXHIBIT 2

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Back to Search Results

Product Details for ANDA 075167

RANITIDINE HYDROCHLORIDE (RANITIDINE HYDROCHLORIDE)
EQ 75MG BASE
Marketing Status: Discontinued

Active Ingredient: RANITIDINE HYDROCHLORIDE
Proprietary Name: RANITIDINE HYDROCHLORIDE
Dosage Form; Route of Administration: TABLET; ORAL
Strength: EQ 75MG BASE
Reference Listed Drug: No
Reference Standard: No
TE Code:
Application Number: A075167
Product Number: 001
Approval Date: May 4, 2000
Applicant Holder Full Name: APOTEX INC
Marketing Status: Discontinued
Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=075167&Appl_type=A)

EXHIBIT 3

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Back to Search Results

Product Details for ANDA 200172

RANITIDINE HYDROCHLORIDE (RANITIDINE HYDROCHLORIDE)
EQ 150MG BASE
Marketing Status: Discontinued

Active Ingredient: RANITIDINE HYDROCHLORIDE
Proprietary Name: RANITIDINE HYDROCHLORIDE
Dosage Form; Route of Administration: TABLET; ORAL
Strength: EQ 150MG BASE
Reference Listed Drug: No
Reference Standard: No
TE Code:
Application Number: A200172
Product Number: 001
Approval Date: May 31, 2012
Applicant Holder Full Name: APOTEX INC
Marketing Status: Discontinued
Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=200172&Appl_type=A)

EXHIBIT 4

COMPANY ANNOUNCEMENT

Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All pack sizes and Formats) due to the potential for Detection of an Amount of Unexpected Impurity,N-nitrosodimethylamine (NDMA) Impurity in the product

Summary

Company Announcement Date:

September 25, 2019

FDA Publish Date:

September 25, 2019

Product Type:

Drugs

Reason for Announcement:

Contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)

Company Name:

Apotex Corp.

Brand Name:

Apotex Corp.

Product Description:

Ranitidine Tablets 75mg and 150mg

Company Announcement

Apotex Corp. is voluntarily, on a precautionary basis, recalling Ranitidine Tablets 75mg and 150mg (All pack sizes and Formats) to the **Retail level**. Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. To date, Apotex has not received any reports of adverse events related to use of the product.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Ranitidine Hydrochloride Tablet is an over the counter (OTC) oral product indicated for the relief of heartburn associated with acid indigestion and sour stomach and prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages. The affected Ranitidine Hydrochloride Tablets can be identified by NDC numbers stated on the product label.

Product	Strength	Pack Size	NDC Number
Ranitidine tablets, USP 150mg- acid reducer (Rite Aid)	150 mg	50's Bottle	11822-6052-1
Ranitidine tablets, USP 150mg- acid reducer (Rite Aid)	150 mg	65's Bottle	11822-6052-2
Ranitidine tablets, USP 150mg- acid reducer (Rite Aid)	150 mg	95's Bottle	11822-4727-3
Ranitidine tablets, USP 150mg- acid reducer (Walmart)	150 mg	65's Bottle	49035-117-06
Ranitidine tablets, USP 150mg- acid reducer (Walmart)	150 mg	24's Bottle	49035-100-00
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	200's Bottle	0363-1030-07

Product	Strength	Pack Size	NDC Number
Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid)	150 mg	24's Bottle	11822-6051-8
Ranitidine tablets, USP 150mg- acid reducer (Walmart)	150 mg	130's Bottle	49035-100-07
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	24's Bottle	0363-1013-02

Product	Strength	Pack Size	NDC Number
Wal-Zan® 75 RANITIDINE TABLETS, USP 75 mg / ACID REDUCER (WALGREENS)	75 mg	30's Bottle	0363-1029-03
Cool mint Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid)	150 mg	24's Bottle	11822-6107-4
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	65's Bottle	0363-1030-06
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	95's Bottle	0363-1030-09

The affected Ranitidine Hydrochloride Tablets were distributed Nationwide to Warehousing Chains. Apotex Corp. has notified its affected direct account Warehousing Chains via mail (FedEx Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product.

Wholesalers, Distributors and Retailers return the impacted product to place of purchase. Anyone with an existing inventory of the product should quarantine the recalled lots immediately. Customers who purchased the impacted product directly from Apotex can call **Inmar Rx Solutions at 800-967-5952 (option 1) (9:00am – 5:00-pm, EST Monday thru Friday), to arrange for their return.**

Consumers with questions regarding this recall can contact Apotex corp. by phone-number 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address **UScustomerservice@Apotex.com** (mailto:UScustomerservice@Apotex.com). **Consumers should contact their physician or healthcare provider** if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Apotex corp.

1-800-706-5575

UScustomerservice@Apotex.com (mailto:UScustomerservice@Apotex.com)

Media:

Jordan Berman

1 (416) 749-9026 Ext. 7487

jberman@apotex.com (mailto: jberman@apotex.com)

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)

EXHIBIT 5

State *of* California Department *of* Justice

XAVIER BECERRA
Attorney General

60 Day Notice 2020-00822

Withdraw Notice Add a Complaint Add a Settlement Add a Judgment

AG Number: 2020-00822

Notice PDF: 2020-00822.pdf

Date Filed: 03/27/2020

Noticing Party: Center for Environmental Health

Plaintiff Attorney: Lexington Law Group

Alleged Violators: Granules Pharmaceuticals, Inc
Granules USA, Inc.
Apotex Corp.

Chemicals: N-Nitrosodimethylamine

Source: OTC Ranitidine Products

60-Day Notice Document

NOTICE OF VIOLATION

California Safe Drinking Water
and Toxic Enforcement Act

N-Nitrosodimethylamine (NDMA) in OTC Ranitidine Products

March 27, 2020

This Notice of Violation (the "Notice") is provided to you pursuant to and in compliance with California Health and Safety Code Section 25249.7(d).

- For general information regarding the California Safe Drinking Water and Toxic Enforcement Act, see the attached summary provided by the California EPA (copies not provided to public enforcement agencies).

- This Notice is provided by the Center for Environmental Health ("CEH"), 2201 Broadway, Suite 508, Oakland, CA 94612, (510) 655-3900. CEH is a nonprofit corporation dedicated to protecting the environment, improving human health, and supporting environmentally sound practices. Caroline Cox is the Senior Scientist of and a responsible individual within CEH.

Description of Violation:

- Violators: The names and addresses of the violators are identified on the attached Exhibit 1.
- Time Period of Exposure: The violations have been occurring since at least March 27, 2017, and are ongoing.
- Provision of Proposition 65: This Notice covers the "warning provision" of Proposition 65, which is found at California Health and Safety Code Section 25249.6.
- Chemical(s) Involved: The name of the listed chemicals involved in these violations is n-nitrosodimethylamine ("NDMA"). Exposures to NDMA occur from ingesting the products identified in this Notice.
- Type of Product: The specific type of product causing these violations is over-the-counter acid reducing medications containing ranitidine ("Ranitidine Products"). A non-exclusive example of this specific type of product is identified on the attached Exhibit 1.
- Description of Exposure: This Notice addresses consumer exposures to NDMA in Ranitidine Products. Taking Ranitidine Products identified in this Notice results in human exposures to NDMA. The primary route of exposure for the violations is direct ingestion when consumers take the Ranitidine Products. No clear and reasonable warning is provided with the Ranitidine Products regarding the carcinogenic hazards of NDMA.

Resolution of Noticed Claims:

Based on the allegations set forth in this Notice, CEH intends to file a citizen enforcement lawsuit against each alleged violator unless such violator agrees in a binding written instrument to: (1) recall products already sold; (2) provide clear and reasonable warnings for products sold in the future or reformulate such products to eliminate the NDMA exposures; and (3) pay an appropriate civil penalty based on the factors enumerated in California Health and Safety Code Section 25249.7(b). If any alleged violator is interested in resolving this dispute without resort to expensive and time-consuming litigation, please feel free to contact CEH through its counsel identified below. It should be noted that CEH cannot: (1) finalize any settlement until after the 60-day notice period has expired; nor (2) speak for the Attorney General or any District or City Attorney who received CEH's 60-day Notice. Therefore, while reaching an agreement with CEH will resolve its claims, such agreement may not satisfy the public prosecutors.

Preservation of Relevant Evidence:

This Notice also serves as a demand that each alleged violator preserve and maintain all relevant evidence, including all electronic documents and data, pending resolution of this matter. Such relevant evidence includes but is not limited to all documents relating to the presence or potential presence of NDMA in Ranitidine Products, purchase and sales information for such products, efforts to comply with Proposition 65 with respect to such products, communications with any person relating to the presence or potential presence of NDMA in such products, and representative samples of each of the products sold by each alleged violator in the year preceding this Notice through the date of any trial or

Supplemental Complaint

AG Number:2020-00822

Complaint PDF: 2020-00822C6584.pdf

Date Filed:01/04/2021

Case Name: CEH v. Perrigo Company, et al.

Court Name: Alameda County Superior Court

Court Docket Number: RG 20-054985

Plaintiff: Center for Environmental Health

Plaintiff Attorney: Lexington Law Group

Defendant: Granules Pharmaceuticals, Inc.

Apotex Corp.

Granules USA, Inc.

Type of Claim: Failure to Warn

Relief Sought: Warning

Civil Penalty

Reformulation

Contact Name: Eric Somers

Contact Organization: Lexington Law Group

Email Address:prop65@lexlawgroup.com

Address: 503 Divisadero Street

City, State, Zip: San Francisco, CA 94117

Phone Number:(415) 913-7800

Comments: Second Amended Complaint

Supplemental Complaint

AG Number:2020-00822

Complaint PDF: 2020-00822C6539.pdf

Date Filed:11/06/2020

Case Name: CEH v. Perrigo Company, et al.

Court Name: Alameda County Superior Court

Court Docket Number: RG 20-054985

Plaintiff: Center for Environmental Health

Plaintiff Attorney: Lexington Law Group

Defendant: 7-Eleven, Inc.

Apotex Corp.

Granules USA, Inc.

Granules Pharmaceuticals, Inc.

Type of Claim: Failure to Warn

Relief Sought: Warning

Civil Penalty

Contact Name: Eric Somers

Contact Organization: Lexington Law Group

Email Address:prop65@lexlawgroup.com

Address: 503 Divisadero Street

City, State, Zip: San Francisco, CA 94117

Phone Number:(415) 913-7800

Comments:

These 4 Defendants were added via First Amended Complaint to an existing action (found here: https://oag.ca.gov/prop65/60-Day-Notice-2020-00018)

EXHIBIT 6

NOTICE OF VIOLATION

California Safe Drinking Water
and Toxic Enforcement Act

N-Nitrosodimethylamine (NDMA) in OTC Ranitidine Products

March 27, 2020

This Notice of Violation (the "Notice") is provided to you pursuant to and in compliance with California Health and Safety Code Section 25249.7(d).

- For general information regarding the California Safe Drinking Water and Toxic Enforcement Act, see the attached summary provided by the California EPA (copies not provided to public enforcement agencies).

- This Notice is provided by the Center for Environmental Health ("CEH"), 2201 Broadway, Suite 508, Oakland, CA 94612, (510) 655-3900. CEH is a nonprofit corporation dedicated to protecting the environment, improving human health, and supporting environmentally sound practices. Caroline Cox is the Senior Scientist of and a responsible individual within CEH.

Description of Violation:

- Violators: The names and addresses of the violators are identified on the attached Exhibit 1.

- Time Period of Exposure: The violations have been occurring since at least March 27, 2017, and are ongoing.

- Provision of Proposition 65: This Notice covers the "warning provision" of Proposition 65, which is found at California Health and Safety Code Section 25249.6.

- Chemical(s) Involved: The name of the listed chemicals involved in these violations is n-nitrosodimethylamine ("NDMA"). Exposures to NDMA occur from ingesting the products identified in this Notice.

- Type of Product: The specific type of product causing these violations is over-the-counter acid reducing medications containing ranitidine ("Ranitidine Products"). A non-exclusive example of this specific type of product is identified on the attached Exhibit 1.

- Description of Exposure: This Notice addresses consumer exposures to NDMA in Ranitidine Products. Taking Ranitidine Products identified in this Notice results in human exposures to NDMA. The primary route of exposure for the violations is direct ingestion when consumers take the Ranitidine Products. No clear and reasonable warning is provided with the Ranitidine Products regarding the carcinogenic hazards of NDMA.

Resolution of Noticed Claims:

Based on the allegations set forth in this Notice, CEH intends to file a citizen enforcement lawsuit against each alleged violator unless such violator agrees in a binding written instrument to: (1) recall products already sold; (2) provide clear and reasonable warnings for products sold in the future or reformulate such products to eliminate the NDMA exposures; and (3) pay an appropriate civil penalty based on the factors enumerated in California Health and Safety Code Section 25249.7(b). If any alleged violator is interested in resolving this dispute without resort to expensive and time-consuming litigation, please feel free to contact CEH through its counsel identified below. It should be noted that CEH cannot: (1) finalize any settlement until after the 60-day notice period has expired; nor (2) speak for the Attorney General or any District or City Attorney who received CEH's 60-day Notice. Therefore, while reaching an agreement with CEH will resolve its claims, such agreement may not satisfy the public prosecutors.

Preservation of Relevant Evidence:

This Notice also serves as a demand that each alleged violator preserve and maintain all relevant evidence, including all electronic documents and data, pending resolution of this matter. Such relevant evidence includes but is not limited to all documents relating to the presence or potential presence of NDMA in Ranitidine Products; purchase and sales information for such products; efforts to comply with Proposition 65 with respect to such products; communications with any person relating to the presence or potential presence of NDMA in such products; and representative exemplars of each of the products sold by each alleged violator in the year preceding this Notice through the date of any trial of the claims alleged in this Notice.

Please direct any inquiries regarding this Notice to CEH's counsel, Mark N. Todzo, at Lexington Law Group, 503 Divisadero Street, San Francisco, CA 94117, (415) 913-7800, mtodzo@lexlawgroup.com.

EXHIBIT 1
March 27, 2020 Notice of Violation
NDMA in OTC Ranitidine Products

Names and Addresses of Responsible Parties	Non-Exclusive Example of the Products	UPC #
Granules Pharmaceuticals, Inc. 3701 Concorde Parkway Chantilly, VA 20151 **Granules USA, Inc.** 111 Howard Blvd., Suite 101 Mount Arlington, NJ 07856 **Apotex Corp.** 2400 North Commerce Parkway, Suite 400 Weston, FL 33326	7 Select Heartburn & Acid Reducer	0-52548-56121-5

CERTIFICATE OF MERIT
Health & Safety Code § 25249.7(d)

I, Mark N. Todzo, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged that the parties identified in the notice have violated Health & Safety Code § 25249.6 by failing to provide clear and reasonable warnings.

2. I am an attorney with the Lexington Law Group, and I represent the noticing party, the Center for Environmental Health.

3. Members of my firm and I have consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposures to the listed chemical that is the subject of the action.

4. Based on the information obtained through those consultations, and on other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that "reasonable and meritorious case for the private action" means that the information provides a credible basis that all elements of the plaintiff's case can be established and the information did not prove that the alleged violators will be able to establish any of the affirmative defenses set forth in the statute.

5. The copy of the Certificate of Merit served on the Attorney General attaches to it factual information sufficient to establish the basis for this certificate, including the information identified in Health & Safety Code § 25249.7(h)(2), i.e., (1) the identity of the persons consulted with and relied on by the certifier, and (2) the facts, studies, or other data reviewed by those persons.

March 27, 2020

Mark N. Todzo
Attorney for CENTER FOR
ENVIRONMENTAL HEALTH

PROOF OF SERVICE

I, Alexis Pearson, declare:

I am a citizen of the United States and employed in the County of San Francisco, State of California. I am over the age of eighteen (18) years and not a party to this action. My business address is 503 Divisadero Street, San Francisco, CA 94117 and my email address is apearson@lexlawgroup.com.

On March 27, 2020, I served the following document(s) on all interested parties in this action by placing a true copy thereof in the manner and at the addresses indicated below:

NOTICE OF VIOLATION OF CALIFORNIA SAFE DRINNKING WATER AND TOXIC ENFORCEMENT ACT;

CERTIFICATE OF MERIT; and

THE SAFE DRINKING AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY (only sent to those on service list marked with an asterisk).

☒ **BY MAIL**: I am readily familiar with the firm's practice for collecting and processing mail with the United States Postal Service ("USPS"). Under that practice, mail would be deposited with USPS that same day with postage thereon fully prepaid at San Francisco, California in the ordinary course of business. On this date, I placed sealed envelopes containing the above mentioned documents for collection and mailing following my firm's ordinary business practices.

Please see attached service list.

☐ **BY FACSIMILE**: I caused all pages of the document(s) listed above to be transmitted via facsimile to the fax number(s) as indicated and said transmission was reported as complete and without error.

☒ **BY ELECTRONIC MAIL**: I transmitted a PDF version of the document(s) listed above via email to the email address(es) indicated on the attached service list [or noted above] before 5 p.m. on the date executed.

Stacey Grassini, Deputy District Attorney
Contra Costa County
900 Ward Street
Martinez, CA 94553
sgrassini@contracostada.org

Michelle Latimer, Program Coordinator
Lassen County
220 S. Lassen Street
Susanville, CA 96130
mlatimer@co.lassen.ca.us

Yen Dang
Supervising Deputy District Attorney
Santa Clara County
70 West Hedding Street, West Wing
San Jose, CA 95110
epu@da.sccgov.org

Allison Haley, District Attorney
Napa County
1127 First Street, Suite C
Napa, CA 94559
CEPD@countyofnapa.org

Stephan R. Passalacqua, District Attorney
Sonoma County
600 Administration Drive, Rm. 212J
Santa Rosa, CA 95403
jbarnes@sonoma-county.org

Phillip J. Cline, District Attorney
Tulare County
221 S. Mooney Avenue, Rm. 224
Visalia, CA 93291
Prop65@co.tulare.ca.us

Paul E. Zellerbach, District Attorney
Riverside County
4075 Main Street
Riverside, CA 92501
Prop65@rivcoda.org

Jeff W. Reisig, District Attorney
Yolo County
301 Second Street
Woodland, CA 95695
cfepd@yolocounty.org

Dije Ndreu, Deputy District Attorney
Monterey County
1200 Aguajito Road
Monterey, CA 93940
Prop65DA@co.monterey.ca.us

Tori Verber Salazar, District Attorney
San Joaquin County
222 E. Weber Avenue, Room 202
Stockton, CA 95202
DAConsumer.Environmental@sjcda.org

Christopher Dalbey, Deputy District Attorney, Santa Barbara County
1112 Santa Barbara Street
Santa Barbara, CA 93101
DAProp65@co.santa-barbara.ca.us

San Francisco City Attorney's Office
City Hall, Room 234
1 Dr. Carlton B. Goodlett Place
Valerie.lopez@sfcityatty.org
San Francisco, CA 94102

Mara W. Elliott, City Attorney
City of San Diego
1200 Third Ave, Suite 700
San Diego, CA 92101
CityAttyCrimProp65@sandiego.gov

Gregory D. Totten, District Attorney
Ventura County
800 South Victoria Avenue
Ventura, CA 93009
daspecialops@ventura.org

Gregory Alker, Assistant District Attorney
San Francisco County
732 Brannan Street
San Francisco, CA 94103
gregory.alker@sfgov.org

Anne Marie Schubert, District Attorney
Sacramento Country
901 G Street
Sacramento, CA 95814
Prop65@sacda.org

Eric J. Dobroth, Deputy District Attorney
San Luis Obispo County
County Government Center Annex, 4th Floor
San Luis Obispo, CA 93408
edobroth@co.slo.ca.us

Jeffrey S. Rosell, District Attorney
Santa Cruz County
701 Ocean Street
Santa Cruz, CA 95060
Prop65DA@santacruzcounty.us

Nancy O'Malley, District Attorney
Alameda County
7776 Oakport Street, Suite 650
Oakland, CA 94621
CEPDProp65@acgov.org

Office of the District Attorney
Calaveras County
891 Mountain Ranch Road
San Andreas, CA 95249
Prop65Env@co.calaveras.ca.us

☐ **BY PERSONAL DELIVERY**: I placed all pages of the document(s) listed above in a sealed envelope addressed to the party(ies) listed above, and caused such envelope to be delivered by hand to the addressee(s) as indicated.

☐ **BY OVERNIGHT DELIVERY**: I deposited such document(s) in a box or other facility regularly maintained by FedEx, or delivered such document(s) to a courier or driver authorized by FedEx, with delivery fees paid or provided for, and addressed to the person(s) being served.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on March 27, 2020 at San Francisco, California.

Alexis Pearson

SERVICE LIST

District Attorney of Alpine County
P.O. Box 248
Markleeville, CA 96120

District Attorney of Amador County
708 Court Street, Ste. 202
Jackson, CA 95642

District Attorney of Butte County
Administration Building
25 County Center Drive
Oroville, CA 95965

District Attorney of Colusa County
346 Fifth Street, Suite 101
Colusa, CA 95932

District Attorney of Del Norte County
450 H Street, Ste. 171
Crescent City, CA 95531

District Attorney of El Dorado County
778 Pacific Street
Placerville, CA 95667

District Attorney of Fresno County
2220 Tulare Street, Ste. 1000
Fresno, CA 93721

District Attorney of Glenn County
P.O. Box 430
Willows, CA 95988

District Attorney of Humboldt County
825 5th Street
Eureka, CA 95501

District Attorney of Imperial County
939 Main Street, Ste. 102
El Centro, CA 92243

District Attorney of Inyo County
P.O. Drawer D
Independence, CA 93526

District Attorney of Kern County
1215 Truxtun Avenue
Bakersfield, CA 93301

District Attorney of Kings County
1400 West Lacey Blvd.
Hanford, CA 93230

District Attorney of Lake County
255 N. Forbes Street
Lakeport, CA 95453

District Attorney of Los Angeles County
Hall of Justice
211 W. Temple Street, Ste. 1200
Los Angeles, CA 90012-3210

District Attorney of Madera County
209 West Yosemite Avenue
Madera, CA 93637

District Attorney of Marin County
3501 Civic Center Drive, Rm. 130
San Rafael, CA 94903

District Attorney of Mariposa County
P.O. Box 730
Mariposa, CA 95338

District Attorney of Mendocino County
P.O. Box 1000
Ukiah, CA 95482

District Attorney of Merced County
2222 "M" Street
Merced, CA 95340

District Attorney of Modoc County
204 S. Court Street, Rm. 202
Alturas, CA 96101-4020

District Attorney of Mono County
P.O. Box 617
Bridgeport, CA 93546

District Attorney of Nevada County
201 Commercial Street
Nevada City, CA 95959

District Attorney of Orange County
401 Civic Center Drive West
Santa Ana, CA 92701

District Attorney of Placer County
10810 Justice Center Drive, Ste. 240
Roseville CA 95678-6231

District Attorney of Plumas County
520 Main Street, Rm. 404
Quincy, CA 95971

District Attorney of San Benito County
419 Fourth Street, 2nd Fl.
Hollister, CA 95023

District Attorney of San Bernardino County
316 N. Mountain View Avenue
San Bernardino, CA 92415

District Attorney of San Diego County
330 West Broadway, Ste. 1300
San Diego, CA 92101

District Attorney of San Mateo County
400 County Center, 3rd Fl.
Redwood City, CA 94063

District Attorney of Shasta County
1355 West Street
Redding, CA 96001

District Attorney of Sierra County
Courthouse
100 Courthouse Sq., 2nd Fl.
Downieville, CA 95936

District Attorney of Siskiyou County
P.O. Box 986
Yreka, CA 96097

District Attorney of Solano County
675 Texas Street, Ste. 4500
Fairfield, CA 94533

District Attorney of Stanislaus County
832 12th Street, Ste. 300
Modesto, CA 95354

District Attorney of Sutter County
446 Second Street
Yuba City, CA 95991

District Attorney of Tehama County
P.O. Box 519
Red Bluff, CA 96080

District Attorney of Trinity County
P.O. Box 310
11 Court Street
Weaverville, CA 96093

District Attorney of Tuolumne County
423 N. Washington Street
Sonora, CA 95370

District Attorney of Yuba County
215 Fifth Street
Marysville, CA 95901

Los Angeles City Attorney's Office
City Hall East
200 N. Main Street, Rm. 800
Los Angeles, CA 90012

San Jose City Attorney's Office
200 East Santa Clara Street
San Jose, CA 95113

Phillip J. Cline, District Attorney
Tulare County
221 S. Mooney Avenue, Rm. 224
Visalia, CA 93291

California Attorney General's Office
Attention: Proposition 65 Coordinator and
Robert Thomas
1515 Clay Street, Ste. 2000
P.O. Box 70550
Oakland, CA 94612-0550

Priyanka Chigurupati, CEO*
Granules Pharmaceuticals, Inc.
3701 Concorde Parkway
Chantilly, VA 20151

Priyanka Chigurupati, CEO*
Granules USA, Inc.
111 Howard Blvd., Suite 101
Mount Arlington, NJ 07856

Jeff Watson, CEO*
Apotex Corp.
2400 North Commerce
Parkway, Suite 400
Weston, FL 33326

EXHIBIT 7

Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

August 2020
Procedural

Contains Nonbinding Recommendations

Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

August 2020
Procedural

Contains Nonbinding Recommendations

TABLE OF CONTENTS

Contains Nonbinding Recommendations

Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to assist holders of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) approved under section 505(c) and 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(c) and (j)), respectively, with submission of marketing status notifications required under section 506I of the FD&C Act (21 U.S.C. 356i). This guidance identifies the required content for these marketing status notifications and the format by which these notifications should be submitted to the Agency.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (Hatch-Waxman Amendments) specifically required FDA to publish and make publicly available, among other things, a list of drug products either approved under section 505(c) of the FD&C Act for safety and effectiveness or approved under section 505(j) of the FD&C Act.[2] FDA fulfills these requirements in its publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[3]

---

[1] This guidance has been prepared by the Office of Generic Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] See section 505(j)(7)(A) of the FD&C Act.

[3] The Orange Book is available at https://www.accessdata.fda.gov/scripts/cder/ob/.

Contains Nonbinding Recommendations

The Orange Book contains different drug product lists, including the "Prescription Drug Product List," the "Over-the-Counter (OTC) Drug Product List," and the "Discontinued Drug Product List."[4] The Prescription Drug Product and OTC Drug Product Lists are sometimes referred to as the *active* section of the Orange Book, and the Discontinued Drug Product List is sometimes referred to as the *discontinued* section of the Orange Book. The discontinued section of the Orange Book sets forth, among other items, drug products (1) that have been identified by the application holder as not being marketed or (2) whose marketing has been discontinued for reasons other than safety or effectiveness, as determined by FDA.[5] When FDA learns that any such drug product is not being marketed, FDA, based on its long-standing practice, moves that drug product from the active section of the Orange Book to the discontinued section of the Orange Book.[6]

FDA regulations require NDA and ANDA holders to notify the Agency of the marketing status of drug products approved under NDAs and ANDAs.[7] The FDA Reauthorization Act of 2017[8] (FDARA) added section 506I to the FD&C Act, which imposes additional marketing status reporting requirements as follows:

- ***Notification of withdrawal from sale*** — requires NDA and ANDA holders to provide a written notification to FDA 180 days prior to withdrawing an approved drug from sale.[9]

- ***Notification of drug not available for sale*** — requires NDA and ANDA holders to provide a written notification to FDA within 180 days of the date of approval of a drug if that drug will not be available for sale within 180 days of the date of approval.[10]

- ***One-time report on marketing status*** — required NDA and ANDA holders to provide a written notification to FDA within 180 days of enactment of FDARA[11] stating whether the NDA and ANDA holder's drug(s) in the active section of the Orange Book

---

[4] See the Orange Book Preface (39th ed., 2019) at vi.

[5] See id.

[6] See id. at xxiv.

[7] See, e.g., 21 CFR 314.81(b)(2)(ii)(*a*) and 314.81(b)(3)(iv).

[8] Public Law 115-52.

[9] Section 506I(a) of the FD&C Act. The statute further states that if a submission under section 506I(a) is not practicable 180 days before withdrawing the product from sale, that submission should be made "as soon as practicable but not later than the date of withdrawal" from sale. Generally, we anticipate that it would be practicable for an application holder to notify FDA immediately after it decides to withdraw the product from sale.

[10] Section 506I(b) of the FD&C Act.

[11] FDARA was enacted on August 18, 2017. This one-time report was due to FDA on Wednesday, February 14, 2018.

> were available for sale or if one or more of the NDA or ANDA holder's drugs in the active section had been withdrawn from sale or had never been available for sale.[12]

In considering whether a drug product has been withdrawn from sale, FDA notes that the Agency has previously indicated that withdrawal from sale is not limited to a permanent withdrawal of a product but can also include "any decision to discontinue marketing of [that] product."[13] In particular, FDA has described its policy on determining whether a product is considered to have been "withdrawn from sale" as follows:

> For purposes of section[] 505(j)(5) and 505(j)(6)(C) of the [FD&C Act], a drug shall be considered to have been 'withdrawn from sale' if the applicant has ceased its own distribution of the drug, whether or not it has ordered recall of previously distributed lots of the drug. A routine, temporary interruption in the supply of a drug product would not be considered a withdrawal from sale, however, unless triggered by safety or effectiveness concerns.[14]

This determination is aided by our review of available information indicating whether a drug product is unavailable, including annual reports. We also note that a drug is considered withdrawn from sale when the application holder ceases its own distribution, even if the application holder plans to eventually return to the market, so long as the application holder has not ceased distribution due to a routine, temporary interruption in supply. Likewise, FDA has considered a drug product to have been withdrawn from sale if the applicable NDA or ANDA holder has notified FDA that the drug product is not being marketed.[15]

Section 506I of the FD&C Act requires FDA to update the Orange Book "based on the information provided" by NDA and ANDA holders in these three marketing status notifications "by moving drugs that are not available for sale from the active section to the discontinued section of [the Orange Book], except that drugs [that are determined to] have been withdrawn from sale for reasons of safety or effectiveness shall be removed from [the Orange Book] in accordance with subsection 505(j)(7)(C)."[16] Also, section 506I of the FD&C Act authorizes FDA to move the NDA and/or ANDA holder's (or holders') drug products from the active section of the Orange Book to the discontinued section if an NDA or ANDA holder fails to submit any of these three marketing status notifications.[17] Application holders are notified electronically that a drug product will be moved to the discontinued section before the move is published in a monthly update.

---

[12] Section 506I(c) of the FD&C Act. As stated in note 11, the one-time update was due on February 14, 2018. Accordingly, this guidance removes the recommendations on submission of this update, which were included in the draft guidance of the same name. The Orange Book was updated, as appropriate, as the one-time updates were reviewed and processed.

[13] See "Abbreviated New Drug Application Regulations," final rule, 57 FR 17950 at 17956 (April 28, 1992).

[14] "Abbreviated New Drug Application Regulations," proposed rule, 54 FR 28872 at 28907 (July 10, 1989).

[15] Orange Book Preface (39th ed., 2019) at xxiv.

[16] Section 506I(e) of the FD&C Act.

[17] Section 506I(d) of the FD&C Act.

Contains Nonbinding Recommendations

III. CONTENT AND FORMAT OF MARKETING STATUS NOTIFICATIONS

The subsequent subsections of this guidance provide information on submitting the marketing status notifications required under section 506I of the FD&C Act to FDA.[18] For each of these notifications, the notification may serve as its own cover letter (i.e., no separate cover letter is needed).

A. Notification of a Withdrawal From Sale

1. Content of the Notification of a Withdrawal From Sale

A notification of a withdrawal from sale must include:

1. The National Drug Code(s) (NDCs) under which the drug is listed (21 CFR part 207)
2. The established name of the drug
3. The proprietary name of the drug, if applicable
4. The NDA or ANDA number
5. The strength of the drug
6. The date on which the drug is expected to no longer be available for sale
7. The reason for the withdrawal[19]

An application holder that markets a drug product under multiple NDCs should only submit notification that the drug product is withdrawn from sale when the application holder has ceased marketing the product under all relevant NDCs. Notification should not be provided if some NDCs are being discontinued but additional NDCs will remain on the market for a particular strength. When notification is provided, the application holder should include a statement of all NDCs being discontinued in its notification to meet the first requirement outlined above. When an application holder is determining the date that a drug product is "expected to no longer be available for sale,"[20] note that FDA generally considers it reasonable for this to be the date on which the application holder will or did cease its own distribution of the drug product, because that is the date the application holder itself has stopped making the drug product available for sale. Applicants should provide an actual date to meet this requirement of the notification (#6). FDA also recommends that the notification include, if known, the last date of manufacturing of the drug product as well as the last date of distribution and lot expiration dates.

[18] Please note that changes to drug product listings that fall outside the scope of this guidance (e.g., a change in ownership or a name change) should be submitted via correspondence to the approved application.

[19] Section 506I(a) of the FD&C Act.

[20] Section 506I(a)(6) of the FD&C Act.

Similarly, an NDA holder that markets both a branded drug product and an authorized generic[21] for that drug product should only submit notification that the drug product is withdrawn from sale when both the branded drug product and the authorized generic will cease marketing.

2. Submission of the Notification of a Withdrawal From Sale

The applicant should submit a notification of a withdrawal from sale in a letter to the applicable NDA or ANDA file through the electronic submissions gateway.[22] The notification should prominently identify the submission as an "**ADMINISTRATIVE CHANGE / NOT AVAILABLE FOR SALE.**" A copy of this Notification of a Withdrawal from Sale submission should be submitted to CDERCollections@fda.hhs.gov for NDAs only. This letter does not replace an application holder's obligation to submit a separate written request under 21 CFR 314.150(c) if it is seeking a voluntary withdrawal of approval of an application or abbreviated application.

As noted above, the notification of a withdrawal from sale is required 180 days prior to withdrawing an approved drug from sale (or if 180 days is not practicable, as soon as practicable but not later than the date of withdrawal).[23] To help keep the Orange Book up to date, these notifications should not be made earlier than 180 days before withdrawing the product from sale.

B. Notification of a Drug Not Available for Sale

1. Content of the Notification of a Drug Not Available for Sale

A notification that a drug is not available for sale within 180 days of the date of approval of the drug must include:

1. The established name of the drug
2. The proprietary name of the drug, if applicable
3. The NDA or ANDA number
4. The strength of the drug
5. The date on which the drug will be available for sale, if known
6. The reason for not marketing the drug after approval[24]

---

[21] An authorized generic "is a listed drug, as defined in [21 CFR 314.3(b)], that has been approved under section 505(c) of the [FD&C Act] and is marketed, sold, or distributed directly or indirectly to the retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug" (21 CFR 314.3(b)).

[22] The electronic submissions gateway is available at https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/. Questions related to electronic submissions should be emailed to the CDER Electronic Submission (ESUB) Team at esub@fda.hhs.gov.

[23] Section 506I(a) of the FD&C Act.

[24] Section 506I(b) of the FD&C Act.

When providing the reason for not marketing the drug after approval, FDA notes that the following examples have been provided as reasons: a lack of demand; a license agreement; an interruption in the supply of drug product components; or issues related to production for a commercial launch at day 180. These examples are not an exhaustive list. FDA also recommends that the notification include, if known, the anticipated start date of manufacturing of the drug product as well as the start date of distribution.

2. Submission of a Notification of a Drug Not Available for Sale

The applicant should submit a notification that a drug will not be available for sale in a letter to the applicable NDA or ANDA file through the electronic gateway. The notification should prominently identify the submission as an "**ADMINISTRATIVE CHANGE / NOT AVAILABLE FOR SALE.**"

We note that if an application holder intends to market within 180 days of the date of approval of a drug, no notification under this section (i.e., the notification that a drug is not available for sale under section 506I(b) of the FD&C Act) to FDA is required.

If an NDA or ANDA holder intends to commence commercial marketing of a drug for which the holder has previously submitted a notification that the drug was not available for sale, FDA recommends that the NDA or ANDA holder notify FDA 30-60 days before the anticipated launch date, which generally is the date the drug product will be introduced or delivered for introduction into interstate commerce, but no later than the date commercial marketing is commenced, in a letter to the applicable NDA or ANDA file through the electronic gateway to ensure that appropriate changes can be made in the Orange Book. The notification should prominently identify the submission as an "**ADMINISTRATIVE CHANGE / NOTIFICATION OF COMMERCIAL MARKETING.**"

EXHIBIT 8

FDA NEWS RELEASE

FDA Requests Removal of All Ranitidine Products (Zantac) from the Market

FDA Advises Consumers, Patients and Health Care Professionals After New FDA Studies Show Risk to Public Health

For Immediate Release:

April 01, 2020

Español (/news-events/press-announcements/la-fda-solicita-el-retiro-del-mercado-de-todos-los-productos-hechos-base-de-ranitidina-zantac)

The U.S. Food and Drug Administration today announced it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation (/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine) of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

"The FDA is committed to ensuring that the medicines Americans take are safe and effective. We make every effort to investigate potential health risks and provide our recommendations to the public based on the best available science. We didn't observe unacceptable levels of NDMA in many of the samples that we tested. However, since we don't know how or for how long the product might have been stored, we decided that it should not be available to consumers and patients unless its quality can be assured," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "The FDA will continue our efforts to ensure impurities in other drugs do not exceed acceptable limits so that patients can continue taking medicines without concern."

NDMA is a probable human carcinogen (a substance that could cause cancer). In the summer of 2019, the FDA became aware of independent laboratory testing that found NDMA in ranitidine. Low levels of NDMA are commonly ingested in the diet, for example NDMA is present in foods and in water. These low levels would not be expected to lead to an increase in the risk of cancer. However, sustained higher levels of exposure may increase the risk of cancer in humans. The FDA conducted thorough laboratory tests and found NDMA in ranitidine at low levels. At the time, the agency did not have enough scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines, and continued its investigation and warned the public in September 2019 (/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs) of the potential risks and to consider alternative OTC and prescription treatments.

New FDA testing and evaluation prompted by information from third-party laboratories confirmed that NDMA levels increase in ranitidine even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers. The testing also showed that the older a ranitidine product is, or the longer the length of time since it was manufactured, the greater the level of NDMA. These conditions may raise the level of NDMA in the ranitidine product above the acceptable daily intake limit.

With today's announcement, the FDA is sending letters to all manufacturers of ranitidine requesting they withdraw their products from the market. The FDA is also advising consumers taking OTC ranitidine to stop taking any tablets or liquid they currently have, dispose of them properly and not buy more; for those who wish to continue treating their condition, they should consider using other approved OTC products. Patients taking prescription ranitidine should speak with their health care professional about other treatment options before stopping the medicine, as there are multiple drugs approved for the same or similar uses as ranitidine that do not carry the same risks from NDMA. To date, the FDA's testing has not found NDMA in famotidine (Pepcid), cimetidine (Tagamet), esomeprazole (Nexium), lansoprazole (Prevacid) or omeprazole (Prilosec).

In light of the current COVID-19 pandemic, the FDA recommends patients and consumers not take their medicines to a drug take-back location but follow the specific disposal instructions in the medication guide or package insert (/drugs/drug-safety-and-availability/medication-guides) or follow the agency's recommended steps (/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know), which include ways to safely dispose of these medications at home.

The FDA continues its ongoing review, surveillance, compliance and pharmaceutical quality efforts across every product area, and will continue to work with drug manufacturers to ensure safe, effective and high-quality drugs for the American public.

The FDA encourages health care professionals and patients to report adverse reactions or quality problems with any human drugs to the agency's MedWatch Adverse Event Reporting (https://www.fda.gov/about-fda/forms/medwatch-fda-safety-information-and-adverse-event-reporting-program-mandatory-html) program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm (https://www.fda.gov/about-fda/forms/medwatch-fda-safety-information-and-adverse-event-reporting-program-mandatory-html); or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media:

Sarah Peddicord (mailto:sarah.peddicord@fda.hhs.gov)

301-796-2805

Consumer:

888-INFO-FDA

Related Information

- Questions and Answers: NDMA impurities in ranitidine (commonly known as Zantac) (/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-ranitidine-commonly-known-zantac)
- What to Know and Do About Possible Nitrosamines in Your Medication (/consumers/consumer-updates/what-know-and-do-about-possible-nitrosamines-your-medication)
- Information about Nitrosamine Impurities in Medications (/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications)

More Press Announcements (/news-events/newsroom/press-announcements)

EXHIBIT 9

U.S. FOOD & DRUG ADMINISTRATION

ANDA 075167

INFORMATION REQUEST

Apotex Corp.
U.S. Agent for Apotex Inc.
2400 North Commerce Parkway
Weston, FL 33326
Attention: Kiran Krishnan
SVP, GRA

Dear Sir:

This letter is in reference to your appoved abbreviated new drug application (ANDA), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ranitidine Tablets USP, 75 mg.

The FDA/CDER/OPQ laboratory has accumulated data that show levels of N-Nitrosodimethylamine (NDMA) above the Acceptable Daily Intake Limit (ADI) in many ranitidine-containing products. In addition, the NDMA levels have been observed to increase in the same batch tested at two time points one to five months apart held at room temperature. The amount of the NDMA increased over time and appeared to be dependent on the formulation and how close the batch was to expiry. In further testing, some products with different formulations were assessed in a stability study. With standard accelerated stability conditions (40°C/75% humidity), elevated levels of NDMA were measured in all products after two weeks. In one formulation under accelerated stability conditions for 30 days, the levels increased to 5000 ng in a 150 mg tablet. FDA observed a high degree of variability in the NDMA content between batches produced by the same manufacturer. NDMA was also observed in the drug substance, where increases in NDMA content over time were noted in lots stored at room temperature.

Based on these data, and other information before the Agency, FDA is no longer confident that any ranitidine drug product will remain stable through its labeled expiration date.

For this reason, FDA requests that you immediately initiate a voluntary withdrawal of all ranitidine drug product batches from the U.S. market. Further, we request that you do not resume marketing of your ranitidine finished product until and unless FDA finds adequate a supplemental application that demonstrates adequate control over NDMA as described below. Your market withdrawal plans, which should include your product withdrawal timeline, should be sent to the designated division recall coordinator in the FDA Office of Regulatory Affairs (ORA) Division of Pharmaceutical Quality Operations (I-IV). These contacts can be found at https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators.

In order to gain approval of a pending application or FDA concurrence to resume distribution of your ranitidine finished drug product into the U.S. market, you must demonstrate acceptable stability of the finished product. Applicants who wish to distribute ranitidine products should 1) evaluate the cause(s) and extent of NDMA (and any other nitrosamine, if present as an impurity) formation over time; 2) as necessary, optimize your formulation and manufacturing controls and/or container/closure design to avert the formation of NDMA on stability, and 3) conduct the following stability studies as described below:

Solid oral dosage forms	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing time points:	30°C/75% ± 5% RH at 0, 3, 6, 9, and 12 months
	40°C/75% ± 5% RH at 0, 1, 2 and 3 months*
Specifications:	Approved stability specifications and test for NDMA
In-Use stability studies:	See below. Only for the product packaged in bottles and not for blister packaging.
Continue the 30°C studies to expiry. The product expiry will be based upon real time data at 30°C. Note: Stability data obtained in the storage conditions described, except in-use studies, will also inform bulk packaging suitability.	
Oral solutions and syrups:	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing time points:	30°C/35% ± 5% RH for the product packaged in semi-permeable containers at 0, 3, 6, 9, and 12 months
	30°C/75% ± 5% RH for other containers at 0, 3, 6, 9, and 12 months
	40°C/75% ± 5% RH at 0, 1, 2 and 3 months
Specifications:	Approved stability specifications and test for NDMA
In-Use stability studies:	See below
Continue the 30°C studies to expiry. The product expiry will be based upon real time data at 30°C.	

Note: Stability data obtained in the storage conditions described, except in-use studies, will also inform bulk packaging suitability.	
Injections:	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing timepoints:	30°C/75% ± 5% RH at 0, 1, 2, and 3 months
	40°C/75% ± 5% RH at 0, 1, 2, and 3 months
Specifications:	Approved stability specifications and test for NDMA
Continue the 30°C studies to expiry. The product expiry will be based upon real time data at 30°C. Note: Stability data obtained in the storage conditions described, except in-use studies, will also inform bulk packaging suitability.	

*40°C/75% ± 5% RH data: If significant change occurs within the first 3 months' testing at the accelerated storage condition, a discussion should be provided to address the effect of short-term excursions outside the label storage condition (e.g., during shipping or handling). See ICH Q1A and USP<1079>.

In-Use Stability studies:	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing time points:	30°C/75% ± 5% RH at 0, 1, 2, 3, and 12 months (or midpoint to expiry). Also, perform the in-use test at the product expiry.
In-Use Study Conditions:	
Open sufficient containers for all analyses, remove induction seal and some amount of tablets, solution, or syrup (to increase head-space as needed); leave desiccant(s) in the container, place reclosed containers in 30°C/35% ± 5% RH chamber (semi-permeable containers) or 30°C/75% RH ± 5% RH chamber (other containers); analyze the In-Use Time = Zero samples unless freshly-manufactured product is being used. Open containers to expose the contents for two minutes every day for a total number of openings/day that correspond to the most frequent dosing regimen in the product labeling. • At initial timepoint 0, 1 month, 2 months, 3 months in-use conditions, test at each month. • Start in-use conditions from month 10 to 12, test at the end of the 12th month (or midpoint to expiry). • Start in-use conditions from month 21 to 23, test at the end of the 23rd month (or up to expiry). In-use stability study should assay NDMA content.	

You should promptly respond in writing to this request to immediately withdraw from distribution any remaining ranitidine batches in US commerce, and to cease further distribution. You should respond no later than April 7, 2020. Facsimile or e-mail responses will not be accepted. In addition, you are reminded that Section 506I(b) of the Federal Food, Drug, and Cosmetic Act requires NDA and ANDA holders to provide a written notification to FDA 180 days prior to withdrawing an approved drug from sale. (See also FDA draft guidance for industry *Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format*; when final, this guidance will reflect FDA's current thinking on this topic.)

The Agency will not approve any pending supplement until FDA finds appropriate controls have been implemented and stability data submitted demonstrating adequate control of drug quality, specifically NDMA. To reintroduce your product to the market, submit a supplemental application with the results of your analysis of the cause(s) and extent of NMDA formation, proposed changes to manufacturing process or other controls, and at least 12 months stability data; 3 months of accelerated stability data; and months 1, 2, and 3 and the 12 month (or midpoint) in-use stability data per the table above. The remaining in-use stability data and other stability data at expiry should be submitted in the next Annual Report.

Prominently identify the submission acknowledging receipt of this communication with the following wording in bold capital letters at the top of the first page of the submission:

INFORMATION REQUEST
QUALITY/COMPLIANCE

If you have any questions, please contact Rey Cantave, Regulatory Business Process Manager, at reynolds.cantave@fda.hhs.gov or 240-402-4035.

Sincerely,

Michael Kopcha -S

Digitally signed by Michael Kopcha -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Michael Kopcha -S, 0.9.2342.19200300.100.1.1=2001873159
Date: 2020.03.31 17:25:43 -04'00'

Michael Kopcha, Ph.D., R.Ph.
Director
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Sincerely,

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -S
Date: 2020.03.31 19:01:45 -04'00'

Donald Ashley, J.D.
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

ANDA 200172

INFORMATION REQUEST

Apotex Corp.
U.S. Agent for Apotex Inc.
2400 North Commerce Parkway
Weston, FL 33326
Attention: Kiran Krishnan
SVP, GRA

Dear Sir:

This letter is in reference to your appoved abbreviated new drug application (ANDA), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ranitidine Tablets USP, 150 mg.

The FDA/CDER/OPQ laboratory has accumulated data that show levels of N-Nitrosodimethylamine (NDMA) above the Acceptable Daily Intake Limit (ADI) in many ranitidine-containing products. In addition, the NDMA levels have been observed to increase in the same batch tested at two time points one to five months apart held at room temperature. The amount of the NDMA increased over time and appeared to be dependent on the formulation and how close the batch was to expiry. In further testing, some products with different formulations were assessed in a stability study. With standard accelerated stability conditions (40°C/75% humidity), elevated levels of NDMA were measured in all products after two weeks. In one formulation under accelerated stability conditions for 30 days, the levels increased to 5000 ng in a 150 mg tablet. FDA observed a high degree of variability in the NDMA content between batches produced by the same manufacturer. NDMA was also observed in the drug substance, where increases in NDMA content over time were noted in lots stored at room temperature.

Based on these data, and other information before the Agency, FDA is no longer confident that any ranitidine drug product will remain stable through its labeled expiration date.

For this reason, FDA requests that you immediately initiate a voluntary withdrawal of all ranitidine drug product batches from the U.S. market. Further, we request that you do not resume marketing of your ranitidine finished product until and unless FDA finds adequate a supplemental application that demonstrates adequate control over NDMA as described below. Your market withdrawal plans, which should include your product withdrawal timeline, should be sent to the designated division recall coordinator in the FDA Office of Regulatory Affairs (ORA) Division of Pharmaceutical Quality Operations (I-IV). These contacts can be found at https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators.

In order to gain approval of a pending application or FDA concurrence to resume distribution of your ranitidine finished drug product into the U.S. market, you must demonstrate acceptable stability of the finished product. Applicants who wish to distribute ranitidine products should 1) evaluate the cause(s) and extent of NDMA (and any other nitrosamine, if present as an impurity) formation over time; 2) as necessary, optimize your formulation and manufacturing controls and/or container/closure design to avert the formation of NDMA on stability, and 3) conduct the following stability studies as described below:

Solid oral dosage forms	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing time points:	30°C/75% ± 5% RH at 0, 3, 6, 9, and 12 months
	40°C/75% ± 5% RH at 0, 1, 2 and 3 months*
Specifications:	Approved stability specifications and test for NDMA
In-Use stability studies:	See below. Only for the product packaged in bottles and not for blister packaging.
Continue the 30°C studies to expiry. The product expiry will be based upon real time data at 30°C. Note: Stability data obtained in the storage conditions described, except in-use studies, will also inform bulk packaging suitability.	
Oral solutions and syrups:	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing time points:	30°C/35% ± 5% RH for the product packaged in semi-permeable containers at 0, 3, 6, 9, and 12 months
	30°C/75% ± 5% RH for other containers at 0, 3, 6, 9, and 12 months
	40°C/75% ± 5% RH at 0, 1, 2 and 3 months
Specifications:	Approved stability specifications and test for NDMA
In-Use stability studies:	See below
Continue the 30°C studies to expiry. The product expiry will be based upon real time data at 30°C. Note: Stability data obtained in the storage conditions described, except in-use studies, will also inform bulk packaging suitability.	

Injections:	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing timepoints:	30°C/75% ± 5% RH at 0, 1, 2, and 3 months
	40°C/75% ± 5% RH at 0, 1, 2, and 3 months
Specifications:	Approved stability specifications and test for NDMA
Continue the 30°C studies to expiry. The product expiry will be based upon real time data at 30°C. Note: Stability data obtained in the storage conditions described, except in-use studies, will also inform bulk packaging suitability.	

*40°C/75% ± 5% RH data: If significant change occurs within the first 3 months' testing at the accelerated storage condition, a discussion should be provided to address the effect of short-term excursions outside the label storage condition (e.g., during shipping or handling). See ICH Q1A and USP<1079>.

In-Use Stability studies	
Number of batches to be placed on stability testing:	3
Stability storage conditions and testing time points:	30°C/75% ± 5% RH at 0, 1, 2, 3, and 12 months (or midpoint to expiry). Also, perform the in-use test at the product expiry.
In-Use Study Conditions:	
Open sufficient containers for all analyses, remove induction seal and some amount of tablets, solution, or syrup (to increase head-space as needed); leave desiccant(s) in the container, place reclosed containers in 30°C/35% ± 5% RH chamber (semi-permeable containers) or 30°C/75% RH ± 5% RH chamber (other containers); analyze the In-Use Time = Zero samples unless freshly-manufactured product is being used. Open containers to expose the contents for two minutes every day for a total number of openings/day that correspond to the most frequent dosing regimen in the product labeling. • At initial timepoint 0, 1 month, 2 months, 3 months in-use conditions, test at each month. • Start in-use conditions from month 10 to 12, test at the end of the 12th month (or midpoint to expiry). • Start in-use conditions from month 21 to 23, test at the end of the 23rd month (or up to expiry). In-use stability study should assay NDMA content.	

You should promptly respond in writing to this request to immediately withdraw from distribution any remaining ranitidine batches in US commerce, and to cease further distribution. You should respond no later than April 7, 2020. Facsimile or e-mail responses will not be accepted. In addition, you are reminded that Section 506I(b) of the Federal Food, Drug, and Cosmetic Act requires NDA and ANDA holders to provide a written notification to FDA 180 days prior to withdrawing an approved drug from sale. (See also FDA draft guidance for industry *Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format*; when final, this guidance will reflect FDA's current thinking on this topic.)

The Agency will not approve any pending supplement until FDA finds appropriate controls have been implemented and stability data submitted demonstrating adequate control of drug quality, specifically NDMA. To reintroduce your product to the market, submit a supplemental application with the results of your analysis of the cause(s) and extent of NMDA formation, proposed changes to manufacturing process or other controls, and at least 12 months stability data; 3 months of accelerated stability data; and months 1, 2, and 3 and the 12 month (or midpoint) in-use stability data per the table above. The remaining in-use stability data and other stability data at expiry should be submitted in the next Annual Report.

Prominently identify the submission acknowledging receipt of this communication with the following wording in bold capital letters at the top of the first page of the submission:

INFORMATION REQUEST
QUALITY/COMPLIANCE

If you have any questions, please contact Rey Cantave, Regulatory Business Process Manager, at reynolds.cantave@fda.hhs.gov or 240-402-4035.

Sincerely,

Michael Kopcha -S

Digitally signed by Michael Kopcha -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Michael Kopcha -S, 0.9.2342.19200300.100.1.1=2001873159
Date: 2020.03.31 18:20:01 -04'00'

Michael Kopcha, Ph.D., R.Ph.
Director
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Sincerely,

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -S
Date: 2020.03.31 19:37:14 -04'00'

Donald Ashley, J.D.
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

EXHIBIT 10

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

_____/

ORDER GRANTING GENERIC MANUFACTUERS' AND REPACKAGERS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION

This matter is before the Court on Defendants Generic Manufacturers' ("Generic Manufacturer Defendants") and Repackagers' ("Repackager Defendants") (collectively "Defendants") Rule 12 Motion to Dismiss on the Ground of Preemption ("Motion to Dismiss"). DE 1582. The Court held a hearing on the Motion to Dismiss on December 15, 2020 ("the Hearing"). The Court has carefully considered the Motion to Dismiss, Plaintiffs' Opposition thereto [DE 1978; DE 2010-1],[1] Defendants' Reply [DE 2133], Plaintiffs' Notice of Supplemental Authority [DE 2488], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Motion to Dismiss is **GRANTED**.

[1] Plaintiffs filed an Opposition at DE 1978 that contains a redaction and filed an unredacted version of the Opposition at DE 2010-1. Citations to the Opposition throughout this Order are to the unredacted version.

I. Factual Background[2]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980's, first by prescription and later as an over-the-counter ("OTC") medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster – the first prescription drug in history to reach $1 billion in sales. *Id.* ¶ 231.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an OTC form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 249-51.

[2] A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor." (quotation marks omitted)). Plaintiffs have set forth their factual allegations in three "master" complaints: the Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, Plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, hundreds of Plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the

Southern District of Florida. In addition, this Court has created a Census Registry where thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. MPIC ¶¶ 1, 6, 19. Plaintiffs allege that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. Plaintiffs are pursuing federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* CCCAC. The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motion to Dismiss pursuant to that schedule.

III. The Master Complaints

Plaintiffs filed three Master Complaints in this MDL: the MPIC, the CCCAC, and the CTPPCC. DE 887, 888, 889. The MPIC raises claims against parties referred to as Generic Manufacturer Defendants that allegedly manufactured generic ranitidine products. MPIC ¶¶ 38-144. The MPIC further raises claims against parties referred to as Repackager Defendants

that allegedly repackaged ranitidine products into different containers and changed "the content on an original manufacturer's label to note the drug [was] distributed or sold under the relabeler's own name," "without manipulating, changing, or affecting the composition or formulation of the drug." *Id.* ¶¶ 211-15. Some of the parties categorized as Generic Manufacturer Defendants are also categorized as Repackager Defendants. *See, e.g., id.* ¶¶ 44, 52. The parties named as Generic Manufacturer Defendants and as Repackager Defendants are not identical among the Master Complaints.

The MPIC contains 15 counts: Strict Products Liability—Failure to Warn, Strict Products Liability—Design Defect, Strict Products Liability—Manufacturing Defect, Negligence—Failure to Warn, Negligence Product Design, Negligent Manufacturing, General Negligence, Negligent Misrepresentation, Breach of Express Warranties, Breach of Implied Warranties, Violation of Consumer Protection and Deceptive Trade Practices Laws, Unjust Enrichment, Loss of Consortium, Survival Actions, and Wrongful Death. Each count is brought against Generic Manufacturer Defendants. All of these counts, other than the Strict Products Liability—Manufacturing Defect and Negligent Manufacturing counts, are also brought against Repackager Defendants.

The CCCAC also raises claims against parties referred to as Generic Manufacturer Defendants and Repackager Defendants. CCCAC ¶¶ 277-357, 416-20. The CCCAC contains 314 counts on behalf of putative nationwide and state classes. The putative nationwide class alleges counts for unjust enrichment, violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq.* ("MMWA"), and common law fraud. The putative state classes allege counts for negligence, battery, product-liability, breach-of-warranty, consumer-protection, and medical-monitoring causes of action.

The CTPPCC raises claims against parties referred to as Generic Manufacturer Defendants. CTPPCC ¶¶ 46-121. The CTPPCC contains nine counts on behalf of a putative nationwide class of Third Party Payors that allegedly paid for prescription medications for others or, alternatively, on behalf of putative state classes. *Id.* ¶¶ 124, 506, 508. The putative class alleges counts of Breach of Express Warranties, Breach of Implied Warranties, Violation of the MMWA, Fraud, Negligent Misrepresentation and Omission, Violations of State Consumer Protection Laws, Unjust Enrichment, and Negligence.[3]

IV. Summary of the Parties' Arguments

Defendants argue in the Motion to Dismiss that all of Plaintiffs' state-law claims against them, regardless of how labeled and pled, are claims for design defect or failure to warn. The Supreme Court has ruled in two significant opinions—*PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013)—that such claims against generic drug manufacturers are pre-empted because they cannot remedy design defects or provide additional warnings while remaining in compliance with federal law. The Supreme Court's rulings apply with equal force to repackagers. Therefore, all of the state-law claims against Defendants must be dismissed. And because Plaintiffs' only federal claims against Defendants, for violations of the MMWA, require a valid state-law warranty claim, the MMWA claims must be dismissed as

[3] The Master Complaints also raise claims against parties referred to as Brand-Name Manufacturer Defendants, Distributor Defendants, and Retailer Defendants. Brand-Name Manufacturer Defendants allegedly manufactured brand-name ranitidine products; Distributor Defendants allegedly purchased ranitidine products in bulk and sold them to Retailer Defendants; and Retailer Defendants allegedly sold ranitidine products to consumers. In addition to the claims described above, the CCCAC and the CTPPCC contain counts for violation of the Racketeer Influenced and Corruption Organizations Act, 18 U.S.C. § 1962(c)-(d), against Brand-Name Manufacturer Defendants. Brand-Name Manufacturer, Distributor, and Retailer Defendants have also brought motions to dismiss based on pre-emption that the Court addresses by separate Orders. The Court refers to Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants collectively as "Manufacturer Defendants." The Court refers to all defendants named in this MDL collectively as "named defendants."

well. Additionally, 21 U.S.C. § 379r prohibits Plaintiffs from obtaining damages in the form of refunds for the purchase of OTC ranitidine products.

Plaintiffs respond that none of their state-law claims against Defendants are pre-empted under *Mensing* and *Bartlett*. Their claims are not pre-empted because the claims are based on the fact that ranitidine products were misbranded when sold and on Defendants' failure to take actions that they could have taken while remaining in compliance with federal law. In addition, Repackager Defendants can be held liable under an absolute-liability theory because they profited from the marketing of ranitidine products. And because Plaintiffs' state-law warranty claims are not pre-empted, the MMWA claims are viable as well. Section 379r does not prohibit Plaintiffs from obtaining damages in the form of refunds for the purchase of OTC ranitidine products.

V. Summary of the Court's Rulings

The design-defect and failure-to-warn claims that the Supreme Court ruled in *Mensing* and *Bartlett* are pre-empted as against generic drug manufacturers are pre-empted as against Defendants, regardless of Plaintiffs' allegations that ranitidine products were misbranded. Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are dismissed with prejudice as pre-empted. Because all of Plaintiffs' counts against Defendants in the Master Complaints incorporate such allegations, all counts against Defendants are dismissed. Plaintiffs' claims against Repackager Defendants that rely on absolute liability are dismissed with prejudice. The Court grants Plaintiffs leave to replead claims based on expiration dates, testing, storage and transportation conditions, warning the FDA, manufacturing defects, and the MMWA, as well as to replead their derivative counts. The Court will address § 379r in a forthcoming Order on

Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law.

VI. Standard of Review

Defendants move to dismiss all of the claims against them under Federal Rule of Civil Procedure 12(b)(6) based on the affirmative defense of federal pre-emption. *See* DE 1582 at 8;[4] DE 2499 at 37; *see also Mensing*, 564 U.S. at 619 (describing federal pre-emption as a drug manufacturer's affirmative defense). A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted). A "complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd en banc*, 764 F.2d 1400 (11th Cir. 1985).

VII. Analysis

An understanding of the law that applies to drugs approved by the FDA is necessary to understand the arguments that the parties make in briefing the Motion to Dismiss. Before turning to the parties' arguments, the Court discusses key statutes and regulations that govern the FDA's

[4] All page number references herein are to the page numbers generated by CM/ECF in the header of each document.

regulation of drugs. The Court next addresses impossibility pre-emption and significant cases that have addressed impossibility pre-emption in the drug context. The Court then turns to the issues raised in the briefing: misbranding, expiration dates and testing, storage and transportation conditions, warning the FDA, manufacturing defects, the MMWA, absolute liability, derivative counts, and express pre-emption under 21 U.S.C. § 379r. For each issue, the Court reviews the arguments of the parties, any relevant allegations in the Master Complaints, and any additional, issue-specific law before providing the Court's analysis and conclusion on the issue.

A. Federal Regulation of Drug Products

The FDA regulates prescription and OTC drugs under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.* ("FDCA"). The FDCA provides a process for the FDA to approve a new drug through a new drug application ("NDA") and a process for the FDA to approve a drug that is the same as a previously approved drug through an abbreviated new drug application ("ANDA"). *See* 21 U.S.C. § 355. A drug must have an FDA-approved NDA or ANDA to be introduced into interstate commerce. *Id.* § 355(a).

1. NDAs

An NDA must contain scientific data and other information showing that the new drug is safe and effective and must include proposed labeling. *See id.* § 355(b)(1). The FDCA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). The FDA may approve the NDA only if it finds, among other things, that the new drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling"; that there is "substantial evidence that the drug will have the effect it purports or is represented to have . . . in the proposed labeling"; that the methods and facilities for manufacturing, processing, and

packaging the drug are adequate "to preserve its identity, strength, quality, and purity"; and that the labeling is not "false or misleading in any particular." *Id.* § 355(d). A drug approved under the NDA process, commonly referred to as a "brand-name drug," is "listed" by the FDA as having been "approved for safety and effectiveness." *See id.* § 355(j)(7). Following the approval of its NDA, a brand-name drug has a certain period of exclusivity in the marketplace. *See id.* § 355(j)(5)(F).

2. ANDAs

Subject to that period of exclusivity, a drug manufacturer may seek the approval of a drug that is identical in key respects to a listed drug by filing an ANDA. *See id.* § 355(j); *Bartlett*, 570 U.S. at 477 (explaining that a generic drug may be approved through the ANDA process "provided the generic drug is identical to the already-approved brand-name drug in several key respects"). A drug approved under the ANDA process is commonly referred to as a "generic drug." The ANDA must contain information showing that the generic drug has the same active ingredient(s), route of administration, dosage form, strength, therapeutic effect, and labeling as the listed drug and is "bioequivalent" to the listed drug. 21 U.S.C. § 355(j)(2)(A). With limited exceptions, the FDA may approve the ANDA only if it finds that the generic drug and its proposed labeling are the same as the listed drug and the listed drug's labeling. *See id.* § 355(j)(4); *see also* 21 C.F.R. § 314.94(a)(8)(iii), (iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug . . . ."). One such exception is that the generic drug's proposed labeling "may include differences in expiration date" from the listed drug. 21 C.F.R. § 314.94(a)(8)(iv).

3. Changes to Drugs with Approved NDAs and ANDAs

The FDA also has requirements for when and how a drug manufacturer may change a drug or drug labeling that has an approved NDA or ANDA. *See id.* §§ 314.70, .97(a). These requirements differ depending on the category of change that the manufacturer seeks to make.

A "major change" is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

Id. § 314.70(b)(1). Such changes include certain labeling changes, changes "in the qualitative or quantitative formulation of the drug product, including inactive ingredients," and changes "in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance." *Id.* § 314.70(b)(2)(i), (iv), (v). A major change requires a "supplement submission and [FDA] approval prior to distribution of the product made using the change." *Id.* § 314.70(b). This supplement is referred to as a "Prior Approval Supplement." *See In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 923 (6th Cir. 2014).

A "moderate change" is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

21 C.F.R. § 314.70(c)(1). The process for making a moderate change is commonly called the "changes-being-effected" process or "CBE" process. *See Mensing*, 564 U.S. at 614. A moderate change generally requires a "supplement submission at least 30 days prior to distribution of the drug product made using the change." 21 C.F.R. § 314.70(c). The drug product with the change

may be distributed prior to FDA-approval, but only after the passage of 30 days from the FDA's receipt of the supplement. *Id.* § 314.70(c)(4). This supplement is referred to as a "Changes Being Effected in 30 Days" supplement. *See id.* § 314.70(c)(3).

However, the FDA may designate certain moderate changes that may be made upon the FDA's receipt of the supplement and need not await the passage of 30 days. *Id.* § 314.70(c)(6). Such changes include certain changes "in the labeling to reflect newly acquired information" and "changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess." *Id.* § 314.70(c)(6)(i), (iii). Where the passage of 30 days is not required, the supplement is referred to as a "Changes Being Effected" supplement. *Id.* § 314.70(c)(3).

Finally, a "minor change" is a change "in the drug substance, drug product, production process, quality controls, equipment, or facilities that ha[s] a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* § 314.70(d)(1). Such a change includes an "extension of an expiration dating period based upon full shelf life data on production batches obtained from" an approved protocol. *Id.* § 314.70(d)(2)(vi). A minor change must be "described in an annual report." *Id.* § 314.70(d).

Despite the availability of these processes to make changes, "generic drug manufacturers have an ongoing federal duty of 'sameness'" that requires "that the warning labels of a brand-name drug and its generic copy must always be the same." *Mensing*, 564 U.S. at 613; *see also* 21 C.F.R. § 314.150(b)(10) (explaining that approval for an ANDA may be withdrawn if the FDA finds that the drug product's labeling "is no longer consistent with that for the listed drug"). Thus, the CBE

process allows "changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Mensing*, 564 U.S. at 614.

B. Impossibility Pre-emption

The Supremacy Clause of the U.S. Constitution provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "It is basic to this constitutional command that all conflicting state provisions be without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (citing *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819)). The pre-emption doctrine is derived from the Supremacy Clause. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

Supreme Court caselaw has recognized that state law is pre-empted under the Supremacy Clause in three circumstances. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). First, "Congress can define explicitly the extent to which its enactments pre-empt state law." *Id.* Second, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.* at 79. Third, state law is pre-empted "to the extent that it actually conflicts with federal law . . . where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citation and quotation marks omitted). Three key Supreme Court opinions have addressed impossibility pre-emption—a subset of conflict pre-emption—in the drug context.

1. *Wyeth v. Levine*

In *Wyeth v. Levine*, a consumer of a brand-name drug sued the brand-name drug manufacturer on negligence and strict-liability theories under Vermont law for failure to provide an adequate warning on the drug's labeling. 555 U.S. 555, 559-60 (2009). The Supreme Court held that the consumer's labeling claims were not pre-empted because the CBE process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the labeling, without waiting for FDA approval. *Id.* at 568-69, 571, 573. The Court stated that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both its federal-law and state-law duties "absent clear evidence that the FDA would not have approved" a labeling change. *Id.* at 571. The brand-name drug manufacturer "offered no such evidence," and the fact that the FDA had previously approved the labeling did "not establish that it would have prohibited such a change." *Id.* at 572-73.

2. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, consumers of generic drugs sued the generic drug manufacturers under Minnesota and Louisiana tort law for failure to provide adequate warnings on the drugs' labeling. 564 U.S. at 610. The Supreme Court held that the consumers' labeling claims were pre-empted because the generic drug manufacturers could not "independently" change the labeling while remaining in compliance with federal law. *Id.* at 618-20, 623-24. The generic drug manufacturers' "duty of 'sameness'" under federal law required them to use labeling identical to the labeling of the equivalent brand-name drug. *Id.* at 613. Thus, the CBE process was unavailable to the generic drug manufacturers to change labeling absent a change to the brand-name drug's labeling. *Id.* at 614-15. Because any change that the generic drug manufacturers made to the drugs'

labeling to comply with duties arising under state tort law would have violated federal law, the state tort claims were pre-empted. *Id.* at 618, 623-24.

The consumers argued, and the FDA asserted in an amicus brief, that even if the generic drug manufacturers could not have used the CBE process to change the labeling, the manufacturers could have "asked the FDA for help" by proposing a labeling change to the FDA. *Id.* at 616, 619. The consumers further argued that their state-law claims would not be pre-empted unless the generic drug manufacturers demonstrated that the FDA would have rejected a proposed labeling change. *Id.* at 620. The generic drug manufacturers conceded that they could have asked the FDA for help. *Id.* at 619.

The Supreme Court rejected the argument that the ability to ask the FDA for help defeated impossibility pre-emption. *Id.* at 620-21. The Court stated that the "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620 (citing *Wyeth*, 555 U.S. at 573). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-24. Asking the FDA for help "would have started a Mouse Trap game" that eventually may have led to a labeling change, "depending on the actions of the FDA and the brand-name manufacturer." *Id.* at 619-20. But, the Court stated, pre-emption analysis that was dependent on what a third party or the federal government might do would render impossibility pre-emption "all but meaningless." *Id.* at 620-21 ("If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.").

3. *Mutual Pharmaceutical Co. v. Bartlett*

In *Mutual Pharmaceutical Co. v. Bartlett*, a consumer of a generic drug brought a design-defect claim under New Hampshire law against a generic drug manufacturer for failure to ensure that the drug was reasonably safe. 570 U.S. at 475. Under New Hampshire law, a drug manufacturer could satisfy its duty to ensure that its drug was reasonably safe "either by changing a drug's design or by changing its labeling." *Id.* at 482, 492. However, because the generic drug manufacturer was unable to change the drug's composition "as a matter of both federal law and basic chemistry," the only way for the manufacturer to fulfill its state-law duty and "escape liability" was by changing the labeling. *Id.* at 475, 483-84 (citing 21 U.S.C. § 355(j) for the proposition that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"). The Supreme Court concluded that, under *Mensing*, federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law, that is, changing the labeling, and therefore the consumer's design-defect claim was pre-empted. *Id.* at 475, 486-87 (citing *Mensing*, 564 U.S. 604).

The First Circuit Court of Appeals had ruled that the generic drug manufacturer could comply with both federal and state law by removing the drug from the market. *Id.* at 475, 479. The Supreme Court stated that this was "no solution" because adopting this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in th[e] Court's pre-emption case law." *Id.* at 475, 488-90 (rejecting the stop-selling rationale as "incompatible" with pre-emption jurisprudence because, in "every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting"). Pre-emption caselaw

"presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488.

4. Application of *Mensing* and *Bartlett*

Based on the *Mensing* and *Bartlett* opinions, federal courts have held that numerous categories of claims against generic drug manufacturers are pre-empted, even where plaintiffs do not couch their claims as design defect or failure to warn. For example, courts have held that claims against generic drug manufacturers for failure to communicate information to consumers or medical providers, where the manufacturers of the listed brand-name drugs have not done so, are pre-empted. *See, e.g.*, *In re Darvocet*, 756 F.3d at 932-33 (concluding that a claim that generic drug manufacturers should have sent letters explaining safety risks to medical providers was pre-empted because, "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading" (quotation marks omitted)); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474-75 (5th Cir. 2014) (concluding that a claim that generic drug manufacturers should have communicated information consistent with the brand-name drug labeling was pre-empted because "the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead" (quotation omitted)); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (concluding that a claim that generic drug manufacturers should have communicated that a labeling change had been made was pre-empted because the manufacturers "were not at liberty" to communicate such information where "no brand-name manufacturer sent a warning based on the . . . label change").

Courts similarly have held that claims against generic drug manufacturers for failure to conduct testing of their drug products are pre-empted. *See, e.g.*, *Drager v. PLIVA USA, Inc.*,

741 F.3d 470, 476-77 (4th Cir. 2014) (concluding that a claim that a generic drug manufacturer was negligent in the "testing, inspection, and post-market surveillance" of its drug product was pre-empted because any duty to perform such acts fell within the "general duty to protect consumers from injury based on the negligent marketing and sale of a product," and the manufacturer "whose product is unreasonably dangerous as sold could not satisfy that [general] duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability"); *Morris*, 713 F.3d at 778 (concluding that a claim that generic drug manufacturers failed to test and inspect their products was pre-empted, in part, because "any 'useful' reporting [of testing results]—at least from the standpoint of those injured—would ostensibly consist of some sort of warning," which the manufacturer could not give).

Courts also have held that claims against generic drug manufacturers for misrepresentation, fraud, and violation of consumer-protection statutes are pre-empted. *See, e.g.*, *In re Darvocet*, 756 F.3d at 935-36 (concluding that fraud, misrepresentation, and consumer-protection claims against generic manufacturers were pre-empted because the claims "all challenge[d] label content," the plaintiffs did "not identify any representations made other than those contained in the FDA-approved labeling," and the manufacturers "could not have corrected any alleged misrepresentation without violating federal law because they were required to conform their labeling to that of the brand-name drugs"); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 680 (5th Cir. 2014) (concluding that consumer-protection claims against generic manufacturers were pre-empted because the claims were based on allegations that the manufacturers failed to sufficiently warn consumers, and federal law forbade the manufacturers from making any changes to their FDA-approved warnings); *Drager*, 741 F.3d at 479 (concluding that negligent misrepresentation and fraudulent concealment claims against a generic drug manufacturer were

pre-empted because they were premised on the content of the labeling, the manufacturer had "no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or truthful," and the manufacturer's "only remaining options [were] to leave the market or accept tort liability").

As one final example, courts have held that claims against generic drug manufacturers for breaches of express and implied warranties are pre-empted. *See, e.g.*, *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013) (concluding that an express-warranty claim against a generic drug manufacturer was pre-empted because the plaintiffs did not identify a mechanism through which the manufacturer "could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness" and that claims for breach of the implied warranties of merchantability and fitness for intended use were pre-empted because the manufacturer "could not have altered the composition of the [drug] it manufactured without violating federal law"); *Drager*, 741 F.3d at 478-79 (concluding that claims that a generic drug manufacturer had breached an express warranty and the implied warranties of merchantability and fitness for a particular purpose were pre-empted because the manufacturer could not have changed its warnings or drug formulation to comply with the warranties and therefore could avoid liability only by leaving the market).

C. Issues

Defendants contend in their Motion to Dismiss that, under *Mensing* and *Bartlett*, all of the claims against them in each of the Master Complaints are pre-empted and must be dismissed. DE 1582 at 8, 10, 16, 27-42. They assert that, even where Plaintiffs have "creatively pled" their claims by calling them something other than design defect or failure to warn, all of the claims are pre-empted design or labeling defect claims "[a]t their core." *Id.* at 8, 22-26, 28. Plaintiffs maintain

that none of their claims are pre-empted. *See generally* DE 2010-1. The Court now turns to the parties' arguments about specific issues and claims.

1. Misbranding

a. Arguments and Allegations

Plaintiffs assert that their claims against Defendants are not pre-empted because they are "parallel to federal misbranding requirements." *Id.* at 32. They incorporate by reference the arguments that they make about misbranding in their Opposition to Brand-Name Defendants' Rule 12 Partial Motion to Dismiss on Preemption Grounds. *Id.*; *see* DE 1976. In that Opposition, Plaintiffs argue that they have alleged in the Master Complaints that ranitidine products were "misbranded" as that term is defined in 21 U.S.C. § 352(a)(1) and (j). DE 1976 at 20-21, 24. The U.S. Code prohibits the introduction of misbranded drugs into interstate commerce. *Id.* at 11, 21. And state laws prohibit the sale of defectively designed drugs. *Id.* at 21. Therefore, because federal law and state laws prohibit the same action, the sale of drugs that are misbranded and dangerous, there is no conflict between federal and state law and no impossibility in complying with both federal and state law. *Id.* at 17, 21-23.

Defendants reply that no other court has recognized Plaintiffs' misbranding argument and that the argument is actually a stop-selling argument, which the Supreme Court rejected in *Bartlett*. DE 2133 at 15-16. If Plaintiffs' misbranding argument were accepted, any plaintiff in a drug case could avoid pre-emption simply by adding misbranding allegations to the complaint. *Id.* at 12-13. Defendants also incorporate by reference the arguments relating to misbranding in Brand-Name Manufacturer Defendants' Reply Brief in Support of Their Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. *Id.* at 15; *see* DE 2134. In that Reply, Brand-Name Manufacturer Defendants add that Plaintiffs have not brought any cause of action

titled "misbranding" in the Master Complaints and that Plaintiffs mention misbranding in only a few causes of action. DE 2134 at 17. Plaintiffs misunderstand the meaning of the federal misbranding statute because a drug product is misbranded only if it fails to contain the FDA-approved labeling. *Id.* at 17-18.

Plaintiffs allege in each Master Complaint that ranitidine products were misbranded because the named defendants "did not disclose NDMA as an ingredient" in the products, "did not disclose the proper directions for storage" of the products, and "did not disclose the proper directions for expiration" of the products. MPIC ¶¶ 421-23; CCCAC ¶¶ 601-03; CTPPCC ¶¶ 338-40. During the Hearing, Plaintiffs clarified that they assert that ranitidine products were misbranded as that term is defined in 21 U.S.C. § 352(a)(1) and (j). DE 2499 at 146.

b. Federal Statutes on Misbranding

The U.S. Code prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded," the "adulteration or misbranding of any . . . drug . . . in interstate commerce," the "receipt in interstate commerce of any . . . drug . . . that is adulterated or misbranded," and the "manufacture within any Territory of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a)-(c), (g). Plaintiffs do not have a private cause of action to enforce this statute. *Id.* § 337(a) (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (explaining that "no private right of action exists for a violation of the FDCA"). Section 352 of the U.S. Code contains several sub-sections delineating the circumstances under which a drug "shall be deemed to be misbranded." 21 U.S.C. § 352. As relevant here, a drug is misbranded if "its labeling is false or misleading in any particular" or if "it is dangerous to health when used in the dosage or manner,

or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." *Id.* § 352(a)(1), (j).

c. Misbranding and *PLIVA, Inc. v. Mensing*

When *Mensing* was pending before the Supreme Court, the United States, in an amicus brief on behalf of the FDA, argued that a drug's labeling must be revised to include a warning "as soon as there is reasonable evidence of an association of a serious hazard with a drug."[5] Brief for the United States as Amicus Curiae Supporting Respondents at 6, 12, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (Nos. 09-933, 09-1039, 09-1501), 2011 WL 741927 (quotation marks omitted). The FDA maintained that, after such evidence is discovered, a drug that lacks an adequate warning is misbranded. *Id.* at 6, 12-13, 23-24 (citing 21 U.S.C. § 352). The FDA recognized that generic drug manufacturers cannot "unilaterally" change drug labeling so as to prevent their drugs from being misbranded. *Id.* at 12, 15-17 (citing 21 U.S.C. § 355(j)(4)(G) and 21 C.F.R. § 314.94(a)(8)(iii)). But the FDA asserted that generic drug manufacturers have "a duty under federal law" to provide the evidence they discover to the FDA and to propose a labeling change to the FDA, for the FDA to then determine whether the labeling should be changed. *Id.* at 12, 14-15, 20. According to the FDA, when a generic drug manufacturer did not fulfill that duty under federal law, a state claim against the manufacturer for failure to warn would not be pre-empted. *Id.* at 14, 30.

In its opinion in *Mensing*, the Supreme Court recognized the FDA's arguments concerning misbranding and, for the purpose of the opinion, assumed that a duty might exist even under federal

[5] This language is derived from 21 C.F.R. § 201.57, which has been amended to read that "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6)(i); *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Rev. 3922-01, 3990 (Jan. 24, 2006) (to be codified at 21 C.F.R. § 201.57). The language cited in the amicus brief, however, continues to apply to "older drugs," meaning drugs for which the FDA approved an NDA before June 30, 2001. *See* 21 C.F.R. §§ 201.56(b)(1)(i),.80(e).

law for a generic drug manufacturer to take action if its drug product is misbranded. *See* 564 U.S. at 616-17 ("Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter."). That, however, did not end the inquiry for the purpose of analyzing federal pre-emption. *See id.* at 617 ("We turn now to the question of pre-emption."). On the issue of impossibility pre-emption, the Court concluded that the consumers' failure-to-warn claims were pre-empted because the generic drug manufacturers could not "independently" change their labeling under federal law and because pre-emption analysis could not depend on what a third party or the federal government might do. *Id.* at 618-21, 623-24 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."). The Court rejected the FDA's premise in its amicus brief that state-law claims are not pre-empted if a drug is misbranded and the drug's manufacturer fails to act. *Cf. id.* at 613 n.3 (noting that, while a court defers to an agency's interpretation of its own regulations, a court does not defer to an agency's ultimate conclusion about whether state law is pre-empted).

The Eighth Circuit Court of Appeals below had determined that a failure-to-warn claim was not pre-empted both because a generic drug manufacturer can propose a labeling change to the FDA and because the manufacturer has the option of withdrawing an insufficiently labeled product from the market. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 608-11 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). While the Supreme Court did not explicitly address this stop-selling argument in its *Mensing* opinion, the Court implicitly rejected the argument by holding that the consumers' failure-to-warn claims were

pre-empted. *See Bartlett*, 570 U.S. at 488-90 (discussing *Mensing*'s rejection of the stop-selling argument).

Following the Supreme Court's opinion in *Mensing*, federal courts presented with claims that generic drug manufacturers had distributed misbranded drugs rejected such claims as pre-empted under *Mensing*. *See, e.g.*, *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 607 (N.D. Miss. 2013) (explaining, where a plaintiff asserted that *Mensing* did not apply to a claim that a manufacturer had distributed a misbranded drug, that "no matter how Plaintiff styles her theories of recovery, her claims ultimately relate to the Generic Defendants' alleged failure to warn about the side effect of metoclopramide"); *Moretti v. PLIVA, Inc.*, No. 2:08-CV-00396-JCM, 2012 WL 628502, at *2, 5 (D. Nev. Feb. 27, 2012) (rejecting a plaintiff's argument that *Mensing* did not foreclose liability based on a generic drug manufacturer continuing to distribute a misbranded drug), *aff'd sub nom. Moretti v. Wyeth, Inc.*, 579 F. App'x 563 (9th Cir. 2014); *Moretti v. Mutual Pharm. Co.*, 852 F Supp. 2d 1114, 1118 (D. Minn. 2012) (stating that the court was "not persuaded" by a plaintiff's attempt to differentiate her misbranding claim from the types of claims addressed in *Mensing* and that, "[d]espite the different 'labels' given these claims, the essence of these claims is that . . . Defendants failed to warn of material safety information concerning metoclopramide"), *aff'd*, 518 F. App'x 486 (8th Cir. 2013); *Metz v. Wyeth, LLC*, No. 8:10-CV-2658-T-27AEP, 2011 WL 50 24448, at *4 (M.D. Fla. Oct. 20, 2011) (dismissing plaintiffs' claim that a generic drug was misbranded because the claim fell "directly within the scope of *Mensing* because it [was] based on Actavis' purported failure to provide an adequate label and package insert for metoclopramide").

d. Misbranding and *Mutual Pharmaceutical Co. v. Bartlett*

When *Bartlett* was pending before the Supreme Court, the United States, in an amicus brief on behalf of the FDA, argued that a "pure" design-defect claim under state law that was based on "new and scientifically significant evidence" not previously before the FDA could "parallel" the federal misbranding statute and might not be pre-empted. Brief for the United States as Amicus Curiae Supporting Petitioner at 12, 20-24, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013) (No. 12-142), 2013 WL 314460 (calling this a "difficult and close" question). The FDA's position was that a "defective-design claim would lie only if based on significant new evidence that triggered a duty under federal law not to market a misbranded drug." *Id.* at 23, 32 (explaining that a state-law duty not to market a misbranded drug "would not conflict with federal law if it appropriately accounted for the FDA's role under the FDCA"). The FDA defined a "pure" design-defect claim as a claim that did "not consider the adequacy of labeling." *Id.* at 12. The FDA opined that the Supreme Court did not need to reach this issue because the New Hampshire law at issue in the case did not recognize "pure" design-defect claims and because the jury below had not been asked to find "new and scientifically significant evidence." *Id.* at 16-17, 20-21, 24.

In its opinion in *Bartlett*, the Supreme Court did "not address state design-defect claims that parallel the federal misbranding statute" because the misbranding statute was "not applicable," as "the jury was not asked to find whether new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous as to be misbranded." *See* 570 U.S. at 487 n.4 (stating that the "parties and the Government appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA"). The Court also rejected the rationale that a drug manufacturer could comply with conflicting state and federal law by stopping selling an unsafe drug. *Id.* at 475,

488 ("Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."). The Court explained that it had rebuffed this stop-selling rationale in *Mensing*. *Id.* at 489-90 ("In concluding that it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same, the Court was undeterred by the prospect that PLIVA could have complied with both state and federal requirements by simply leaving the market." (citation and quotation marks omitted)).

Following the Supreme Court's opinion in *Bartlett*, some federal courts have been presented with misbranding claims against drug manufacturers and have rejected the claims either because the law of the state at issue did not recognize a "pure" design-defect claim or because the misbranding claim was not based on new and scientifically significant evidence that was not before the FDA. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 299 n.3 (6th Cir. 2015) (concluding that a plaintiff could not "stave off preemption" by mentioning misbranding where she had not cited any new and scientifically significant evidence not before the FDA); *In re Darvocet*, 756 F.3d at 929-30 (explaining that the plaintiffs failed to identify a state claim that had elements identical to a federal misbranding claim and failed to point to new and scientifically significant evidence that the generic drug manufacturers possessed that was not before the FDA); *Schrock*, 727 F.3d at 1290 (stating that the plaintiffs had not advanced a misbranding claim that was based on new and scientifically significant information not before the FDA); *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2015 WL 7272766, at *4 (S.D. Ill. Nov. 18, 2015) (determining that the plaintiff could not "assert a 'pure' design defect claim under Illinois law"). However, none of these cases have ruled on the issue that the Supreme Court declined to address in *Bartlett*: whether a claim based on an allegation

that a drug was misbranded escapes pre-emption if the claim is brought under the law of a state that recognizes a "pure" design-defect claim and is based on new and scientifically significant evidence not before the FDA. *See, e.g.*, *In re Darvocet*, 756 F.3d at 929 (declining to resolve the "possibly thorny issue" of whether a misbranding claim creates an exception to impossibility pre-emption because the plaintiffs "failed to plead such a claim"); *see also Bartlett*, 570 U.S. at 487 n.4.

e. Analysis and Conclusion

No court has adopted Plaintiffs' theory that impossibility pre-emption can be avoided by showing that a drug is misbranded. *Mensing* and *Bartlett* dictate that Plaintiffs' claims are pre-empted if they are based on alleged product defects that Defendants could not independently change while remaining in compliance with federal law, even if those defects rendered the products misbranded. *Mensing* and *Bartlett* further instruct that the ability to comply with both federal and state law by withdrawing misbranded ranitidine products from the market does not defeat pre-emption. A claim based on an allegation that a generic drug's labeling renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change FDA-approved labeling.[6] *See Mensing*, 564 U.S. at 618-21. Likewise, a claim based on an allegation that a generic drug's formulation renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved. *See Bartlett*, 570 U.S. at 483-84 (citing 21 U.S.C. § 355(j)).

[6] The Court takes no position as to whether state-law claims would be pre-empted where a drug product was misbranded because it did not contain the FDA-approved labeling. Plaintiffs have not alleged or argued that any ranitidine products did not contain the FDA-approved labeling. A circuit split exists on the issue of whether a claim based on failure to use FDA-approved labeling is pre-empted. *See Wagner v. Teva Pharms. USA, Inc.*, 840 F.3d 355, 359-60 & n.1 (7th Cir. 2016) (noting this split of authority between the Fifth and Sixth Circuits and declining to take a position, citing *Morris*, 713 F.3d 774 and *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013)).

The fact that federal law imposes criminal liability on a drug manufacturer that introduces a misbranded drug into interstate commerce is of no matter. *See* 21 U.S.C. §§ 331(a)-(c), (g), 333 (providing penalties for misbranding crimes). It does not follow that, because a drug manufacturer that introduces a misbranded drug into interstate commerce is subject to criminal liability, a civil remedy must also be available. There is no private cause of action to enforce the federal misbranding statutes. *See id.* § 337(a); *Ellis*, 311 F.3d at 1284 n.10.

A finding that Plaintiffs can avoid pre-emption by alleging that defects in ranitidine products made the products misbranded under 21 U.S.C. § 352 would render the vast body of pre-emption caselaw in the drug context, including binding Supreme Court decisions, meaningless. If Plaintiffs' position were accepted, a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was "false or misleading in any particular" or that the drug was "dangerous to health when used" as prescribed. *See* 21 U.S.C. § 352(a)(1), (j). The Court cannot adopt a position that would render pre-emption caselaw meaningless. *Cf. Bartlett*, 570 U.S. at 488-90 (rejecting the stop-selling rationale because it was "incompatible with our pre-emption jurisprudence," would mean that the vast majority or all "of the cases in which the Court has found impossibility pre-emption, were wrongly decided," and would make impossibility pre-emption "all but meaningless" (quotation marks omitted)); *Mensing*, 564 U.S. 620-21 (rejecting the proposition that pre-emption analysis could be dependent on what a third party or the federal government might do because such a position would "render conflict pre-emption largely meaningless").

Thus, Plaintiffs' claims based on alleged defects in ranitidine products, product labeling, or other communications that Generic Manufacturer Defendants could not independently change while remaining in compliance with federal law are pre-empted. This includes, but is not limited to, claims based on allegations that ranitidine products were defectively designed because they

break down into NDMA and claims based on failure to warn consumers that the products contained NDMA or could break down into NDMA when ingested. *See, e.g.*, MPIC ¶¶ 461, 478, 508, 522, 551, 566, 579, 593, 617, 630; *see also* 21 U.S.C. § 355(j)(2)(A) (requiring generic drug products to have the same active ingredient(s), route of administration, dosage form, strength, therapeutic effect, and labeling as the listed drug and be bioequivalent to the listed drug). The Court finds it unnecessary to identify every allegation in the 7,236 numbered paragraphs in the Master Complaints involving an action that Generic Manufacturer Defendants could not independently and lawfully take. The Court places confidence in the ability of Plaintiffs' counsel to, in good faith, identify these allegations and to omit them from claims against Generic Manufacturer Defendants upon repleading the Master Complaints.

Plaintiffs do not contend that Repackager Defendants could lawfully make product or labeling changes that Generic Manufacturer Defendants could not lawfully make. The same pre-empted claims against Generic Manufacturer Defendants are likewise pre-empted as against Repackager Defendants.

Finally, Brand-Name Manufacturer Defendants assert in their Reply Brief in Support of Their Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law (which Defendants incorporate by reference) and argued during the Hearing that a drug product is misbranded only if it fails to contain the FDA-approved labeling. DE 2134 at 17-18; DE 2499 at 126, 130; *see* DE 2133 at 15. Defendants and Brand-Name Manufacturer Defendants have not pointed to any authority providing that definition of misbranding. The statute delineating when a drug is misbranded does not contain the definition that Defendants and Brand-Name Manufacturer Defendants propose. *See* 21 U.S.C. § 352. Nor is it apparent that the FDA defines misbranding in such a way, as the FDA maintained in its amicus brief in *Bartlett* that a drug may

be misbranded if new and scientifically significant information concerning the drug's safety comes to light. *See* Brief for the United States as Amicus Curiae Supporting Petitioner at 21-22, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013) (No. 12-142), 2013 WL 314460 (citing 21 U.S.C. § 352(j)).

The Court does not resolve this issue. For the purpose of this Order, the Court assumes, without finding, that Plaintiffs have adequately alleged that ranitidine products were misbranded. The Court nevertheless concludes that Plaintiffs' allegations of misbranding have no bearing on the holdings of *Mensing* and *Bartlett*.

Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are dismissed with prejudice as pre-empted. Because all of Plaintiffs' counts against Defendants in the Master Complaints incorporate such allegations, all counts against Defendants are dismissed.

2. Expiration Dates and Testing

a. Arguments and Allegations

Plaintiffs contend that there was at least one piece of information on the packaging of ranitidine products that Defendants could change without FDA pre-approval, that is, the expirations dates for the products.[7] DE 2010-1 at 13-18. Under federal law, an expiration date for a generic product need not be the same as the expiration date for the listed brand-name drug. *Id.* at 12, 16-18, 20, 26-27. Defendants could and should have shortened the expiration dates for ranitidine products because the products did not remain "stable" through the expiration dates on

[7] Plaintiffs cite to evidence outside of the Master Complaints to support this point. DE 2010-1 at 27-28. The Court disregards this evidence for the purpose of ruling on the Motion to Dismiss. *See Bickley v. Caremark RX, Inc.*, 461 F.3d 1325, 1329 n.7 (11th Cir. 2006) (stating that a court considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "generally is limited to reviewing what is within the four corners of the complaint," but may consider documents referred to in the complaint if those documents are central to the plaintiff's claim); *see also* Fed. R. Civ. P. 12(d) (requiring a motion to dismiss under Rule 12(b)(6) to be treated as a motion for summary judgment under Rule 56 if "matters outside the pleadings are presented to and not excluded by the court").

the packaging and developed higher levels of NDMA as time passed. *Id.* at 25-26. Defendants could have known that expiration dates for ranitidine products should have been shorter had they conducted adequate testing of their products. *Id.* at 11-13, 21, 26. Thus, Plaintiffs can pursue state-law claims that are based on failure to warn that ranitidine products had expired and failure to test the products to learn of their expiration. *Id.* at 9, 20, 22-23.

Defendants, citing to some of the same cases that the Court cites in Section VII.B.4. of this Order, argue that federal courts have ruled that claims against generic drug manufacturers for failure to conduct testing of their drug products are pre-empted. DE 1582 at 25-26, 37; DE 2133 at 7, 17-19; *see, e.g.*, *Drager*, 741 F.3d at 476-77; *Morris*, 713 F.3d at 778. Plaintiffs' allegations and arguments about shortening expiration dates are "fundamentally inconsistent" with other allegations in the Master Complaints and are "irrelevant" because "Plaintiffs' claims are grounded in the theory that the labeling was deficient because it did not warn of the risk of cancer or the presence of NDMA, that there is *no* safe level of NDMA, and that *all* ranitidine medications contain elevated levels of NDMA." DE 2133 at 7, 19-21.

Plaintiffs allege in the MPIC that stability testing of a drug determines the appropriate expiration date for the drug and that continued stability testing verifies that the expiration date remains appropriate. MPIC ¶¶ 371, 373. Stability testing that the FDA conducted "revealed NDMA levels were higher as [ranitidine] products approached their expiration dates" and "raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels." *Id.* ¶¶ 302, 407. This testing "eroded the [FDA's] confidence that any ranitidine-containing product could remain stable through its labeled expiration date," and therefore the FDA "withdrew the products from the market." *Id.* ¶ 302. The named defendants "did not conduct adequate stability testing of their product to ascertain . . .

expiration" and did not communicate appropriate expiration dates. *Id.* ¶¶ 467, 481(e), (j), 552. The named defendants could have provided appropriate expiration dates and had a duty to provide appropriate expiration dates. *Id.* ¶¶ 457, 486. The named defendants would have known of the danger that ranitidine products posed had they properly tested the products. *Id.* ¶¶ 460, 507. Alternatively, Plaintiffs allege that the named defendants did test ranitidine products and did know of the danger that the products posed, but nevertheless continued to market the products. *Id.* ¶¶ 450-51, 454, 460, 507, 556(t). Plaintiffs make similar allegations in the CCCAC and the CTPPCC.

b. Federal Regulations on Expiration Dates and Testing

"There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates." 21 C.F.R. § 211.166(a). "To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing . . . ." *Id.* § 211.137(a). "Expiration dates shall be related to any storage conditions stated on the labeling . . . ." *Id.* § 211.137(b). The expiration date on the proposed labeling included in an ANDA for a generic drug need not be the same as the expiration date for the listed drug. *Id.* § 314.94(a)(8)(iv).

According to FDA guidance that the parties cite, a "[r]eduction of an expiration dating period to provide increased assurance of the identity, strength, quality, purity, or potency of the drug product" is a moderate change that may be made through the CBE process. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry: Changes to an Approved NDA or ANDA (April 2004),

https://www.fda.gov/media/71846/download.[8] None of the parties have pointed to any case where a claim based on failure to shorten the expiration date for a drug has been presented to a court.

c. Analysis and Conclusion

The Supreme Court explained in *Wyeth v. Levine* that a failure-to-warn claim is not pre-empted if a drug manufacturer has the ability to change drug labeling through the CBE process without waiting for FDA approval, unless there is evidence that the FDA would reject the change. 555 U.S. at 568-73. Therefore, if it is accepted that the expiration date for a generic drug need not be the same as for the listed brand-name drug, and if it is accepted that a generic drug manufacturer can shorten the expiration dates on its drug products through the CBE process without FDA pre-approval, then Plaintiffs might be able to bring claims based on the expiration dates for ranitidine products that are not pre-empted.

However, the Master Complaints do not state claims based on expiration dates and testing upon which relief can be granted. First, Plaintiffs have not pled any counts in the Master Complaints that are devoted to expiration dates or to testing. Plaintiffs instead incorporate their allegations about expiration dates and testing, along with all of their other allegations, into every one of their counts.

Second, Plaintiffs have not identified in the Master Complaints the state-law duty or duties for each of the 52 jurisdictions that they maintain Defendants did not fulfill when they did not shorten expiration dates for ranitidine products. By the Court's understanding, Plaintiffs raise their allegations concerning expiration dates under the duty to warn, the duty to test, or both. *See, e.g.*, MPIC ¶¶ 467, 481(j), 552. Some states recognize negligent testing as a tort that is independent of

[8] The parties agree that the Court may take judicial notice of this FDA guidance manual and consider it at the motion-to-dismiss stage. DE 2499 at 38-39; *see Gustavsen v. Alcon Lab'ys, Inc.*, 272 F. Supp. 3d 241, 252-53 (D. Mass. 2017) (explaining that it is proper for courts to take judicial notice of public documents such as material appearing on government websites, and considering material on the FDA's website on a motion to dismiss).

design-defect, manufacturing-defect, and failure-to-warn claims, while other states do not. *Compare Atkinson v. Luitpold Pharms., Inc.*, 448 F. Supp. 3d 441, 453-54 (E.D. Pa. 2020) (citing Texas caselaw for the proposition that "in Texas there is an independent cause of action based on negligent failure to test"), *with Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989) (concluding that, under Minnesota law, a manufacturer's duty to inspect and test its products is subsumed within the duties to safely design, safely manufacture, and adequately warn). Plaintiffs have not identified in the Master Complaints which duties under which states' laws apply to Generic Manufacturer Defendants, Repackager Defendants, or both.

Third, Plaintiffs have not brought their state-law claims in the MPIC and the CTPPCC in separate counts by jurisdiction. Instead, each count in the MPIC and the CTPPCC that raises a state-law claim is brought under the laws of many or all of the 52 jurisdictions—50 states, Puerto Rico, and the District of Columbia—at issue in this MDL. To provide needed clarity as to their allegations, upon repleading Plaintiffs should bring all claims arising under separate states' laws in separate counts in each of the Master Complaints. *See* Fed. R. Civ. P. 10(b) ("If doing so would promote clarity, each claim founded on a separate transaction or occurrence . . . must be stated in a separate count or defense.").

As Defendants point out, Plaintiffs' allegations that expiration dates for ranitidine products should have been shortened because the products became dangerous over time are inconsistent with their allegations that the products were dangerous upon being manufactured. *See, e.g.*, MPIC ¶¶ 345, 476 (alleging that ranitidine products were "inherently dangerous" "[a]t all relevant times" and that testing has revealed that the products contain "elevated levels of NDMA" after two weeks). Pleading in the alternative is permissible. Fed. R. Civ. P. 8(d)(2) ("A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count

or defense or in separate ones."); *Adinolfe v. United Techs. Corp.*, 768 F.3d 1161, 1175 (11th Cir. 2014) ("It is a well-settled rule of federal procedure that plaintiffs may assert alternative and contradictory theories of liability."). However, a party may not plead internally inconsistent facts within a count. *See Campos v. Immigr. & Naturalization Serv.*, 32 F. Supp. 2d 1337, 1343 (S.D. Fla. 1998) (explaining that a court need not accept internally inconsistent factual allegations in a complaint); *see also Joseph v. Chronister*, No. 8:16-cv-274-T-35CPT, 2019 WL 8014507, at *9 (M.D. Fla. Jan. 3, 2019) (determining that a plaintiff permissibly pled in the alternative where his inconsistent factual allegations were pled in separate counts); *McMahon v. City of Riviera Beach*, No. 08-80499-CIV, 2008 WL 4108051, at *3 (S.D. Fla. Aug. 28, 2008) (concluding that a plaintiff's incorporation of inconsistent factual allegations within counts was "fatal" to the counts). Plaintiffs' incorporation of inconsistent factual allegations into their counts is improper.

Finally, the Court addresses an issue raised during the Hearing. Plaintiffs asserted that "preemption applies only to the extent of the difference between state and Federal responsibilities." DE 2499 at 26-27. Plaintiffs explained that, if "a state cause of action creates duties A, B, and C, and Federal law makes it impossible to comply with duty C," then a plaintiff "can still plead and prove her case based on either . . . a breach of duty A, or a breach of duty B," and there "is only preemption to the extent of the difference." *Id.* at 27. To support their assertion, Plaintiffs pointed to statements in Supreme Court opinions such as *Reigel v. Medtronic, Inc.*, *Bates v. Dow Agrosciences LLC*, and *Medtronic, Inc v. Lohr*. *See Reigel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) ("State requirements are pre-empted under [21 U.S.C. § 360k(a) of the Medical Device Amendments of 1976] only to the extent that they are different from or in addition to the requirements imposed by federal law." (quotation marks omitted)); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 453 (2005) (remanding for a lower court to determine whether a provision of

the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), expressly pre-empted Texas fraud and failure-to-warn claims and stating that, "were the Court of Appeals to determine that the element of falsity in Texas' common-law definition of fraud imposed a broader obligation than FIFRA's requirement that labels not contain 'false or misleading statements,' that state-law cause of action would be pre-empted by § 136v(b) to the extent of that difference"); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (explaining that "additional elements" of a state-law cause of action that "make the state requirements narrower, not broader, than the federal requirement" do not necessarily render the cause of action different from federal law and expressly pre-empted under 21 U.S.C. § 360k(a) of the Medical Device Amendments of 1976).

Reigel, *Bates*, and *Lohr* did not address impossibility pre-emption. In each case, the Supreme Court examined a statutory provision that expressly pre-empted state law that was "different from" federal law, and therefore state law was pre-empted only to the extent of its difference from federal law. *See* 7 U.S.C. § 136v(b) ("Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."); 21 U.S.C. § 360k(a) (providing that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device"); *see also English*, 496 U.S. at 78 (explaining that express pre-emption exists when Congress "define[s] explicitly the extent to which its enactments pre-empt state law").

During the Hearing, the parties agreed that impossibility pre-emption exists when state law imposes a duty or obligation on a party to do something, but federal law prevents the party from doing it. DE 2499 at 38. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 618, 620

(finding impossibility where it "was not lawful under federal law for the Manufacturers to do what state law required of them"); *see also English*, 496 U.S. at 79 (explaining that impossibility pre-emption exists when "it is impossible for a private party to comply with both state and federal requirements"). If a defendant cannot, independently and while remaining in compliance with federal law, do what needs to be done to avoid liability under a state cause of action, the cause of action is pre-empted. *See Bartlett*, 570 U.S. at 486-87 (concluding that a state-law design-defect claim was pre-empted because federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law). Upon any repleading, Plaintiffs should consider, as to each cause of action, the elements under each state's law and what state law would require of Defendants to avoid liability.

For the reasons given herein, Plaintiffs' claims based on allegations that Defendants should have shortened the expiration dates on ranitidine products or should have conducted testing of the products are dismissed without prejudice and with leave to amend.

3. Storage and Transportation Conditions

a. Arguments and Allegations

Defendants contend that any claims that they should have placed different storage and transportation information on ranitidine product labeling or "implemented" different storage and transportation conditions for the products are pre-empted. DE 1582 at 29, 36. This is so because Defendants could not independently and lawfully change FDA-approved labeling, including any storage and transportation information on labeling, and because they were bound to comply with the storage and transportation instructions on labeling. *Id.* at 29, 36.

Plaintiffs respond that they "do not accept" Defendants' assertion that they could not lawfully change storage and transportation information listed on the labeling for ranitidine

products. DE 2010-1 at 39. At this stage of the litigation, the Court must accept as true Plaintiffs' allegations that Defendants could have changed storage and transportation information on the labeling and could have learned of the appropriate storage and transportation information through stability testing. *Id.* at 23, 39.

Plaintiffs allege in the MPIC that adequate stability testing of ranitidine products would have revealed the appropriate storage and transportation conditions for the products, including the appropriate conditions relating to temperature and exposure to light. MPIC ¶¶ 371, 407, 481(j), 556(g). The named defendants failed to conduct adequate stability testing of ranitidine products. *Id.* ¶¶ 481(j), 523(e), 556(g). Ranitidine products contained "false and misleading" storage and transportation information on the labeling, and the named defendants did not attempt to correct that information or to add the proper storage and transportation information. *Id.* ¶¶ 383, 385, 388, 414, 422, 481(g). The named defendants had a duty to communicate appropriate storage and transportation information for ranitidine products, and they breached that duty. *Id.* ¶¶ 414, 457. In addition, the Manufacturer Defendants failed to "implement appropriate handling instructions and storage conditions" for ranitidine products. *Id.* ¶¶ 496(e), 536(e). Plaintiffs make similar allegations in the CCCAC and the CTPPCC.

b. Relevant Federal Law

As already explained, an ANDA must contain information showing that the generic drug has the same labeling as the labeling approved for the listed drug. 21 U.S.C. § 355(j)(2)(A)(v), (4)(G); *see also* 21 C.F.R. § 314.94(a)(8)(iv). According to FDA guidance, a "[c]hange in the labeled storage conditions, unless exempted by regulation or guidance" is a major change that requires the submission of a Prior Approval Supplement and FDA approval. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and

Research, Guidance for Industry: Changes to an Approved NDA or ANDA (April 2004), https://www.fda.gov/media/71846/download. Claims that are based on alleged labeling defects that a defendant could not independently change while remaining in compliance with federal law are pre-empted. *Mensing*, 564 U.S. at 618-21, 623-24.

c. Analysis and Conclusion

The Court is not aware of any authority standing for the proposition that storage and transportation information on FDA-approved labeling for a generic drug is treated differently than other labeling information that must match what the FDA has approved for the listed brand-name drug. For example, the Court knows of no authority providing that the FDA may approve proposed labeling in an ANDA if it adds, omits, or contains different storage and transportation information from the FDA-approved brand-name labeling. The Court similarly is not aware of any authority providing that generic drug manufacturers or repackagers can change storage and transportation information on labeling without FDA pre-approval while remaining in compliance with federal law. In addition, Plaintiffs acknowledged during the Hearing that "changing the storage and transport conditions to the extent that it could impact the identity, quality, and purity profile of the drug and pose risk to the ultimate consumer would constitute a major change." DE 2499 at 46.

Because claims based on labeling defects that a defendant cannot independently change while remaining in compliance with federal law are pre-empted, Plaintiffs' claims based on allegations that Defendants should have placed different or additional storage and transportation information on their ranitidine products' labeling are dismissed with prejudice as pre-empted. In addition, Plaintiffs claims based on allegations that Defendants should have conducted better testing of ranitidine products to enable them to provide the appropriate storage and transportation information on labeling are dismissed with prejudice as pre-empted. *See, e.g.*, *Morris*, 713 F.3d at

778 (concluding that a claim that generic drug manufacturers failed to test and inspect their products was pre-empted because the manufacturers could not have used the testing results to independently make a change to the products); *Metz v. Wyeth, LLC*, 872 F. Supp. 2d 1335, 1342 (M.D. Fla. 2012) (concluding that a claim that a generic drug manufacturer failed to conduct adequate testing was pre-empted under *Mensing* because, even if the manufacturer had conducted adequate testing, it could not have independently furnished the testing results to consumers or the medical community).

During the Hearing, Plaintiffs clarified that, by pleading that Defendants failed to "implement appropriate handling instructions and storage conditions" for ranitidine products, Plaintiffs meant that "Defendants kept [r]anitidine products under the wrong conditions within their own facilities." DE 2499 at 46; *see also* MPIC ¶¶ 496(e), 536(e). Plaintiffs asserted that they have plausibly pled that Defendants, as well as other named defendants, did not adhere to the proper storage and transportation conditions for ranitidine products. DE 2499 at 46, 51, 78, 114-15. Plaintiffs pointed to their allegations in paragraphs 407, 409, and 457 of the MPIC. *Id.* at 114-15. They acknowledged that they do not know what actions any named defendant took that resulted in ranitidine products being kept under the incorrect conditions, but Plaintiffs asserted that they should be permitted to learn this information through discovery. *Id.* at 50-51, 77, 114-15, 119

The Court declines to determine at this juncture whether a state-law claim for failure to store ranitidine products under the correct conditions is pre-empted. This is because, to the extent that it is Plaintiffs' intent to hold Defendants liable for storing ranitidine products under the wrong conditions, such a theory is not pled. Paragraphs 407, 409, and 457 of the MPIC do not allege that Defendants stored ranitidine products under the wrong conditions. *See* MPIC ¶¶ 407, 409, 457. The paragraphs certainly do not plead specific facts such as the identification of which named

defendants kept ranitidine products under the wrong conditions or of how the conditions under which any products were kept differed from what Plaintiffs maintain were the proper storage conditions. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007) (requiring a complaint to provide sufficient factual allegations to "state a claim to relief that is plausible on its face" and to "raise a right to relief above the speculative level"); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (stating that a complaint must offer more than labels, conclusory statements, and naked assertions devoid of factual enhancement to plead a claim upon which relief can be granted).

To the extent that Plaintiffs, upon repleading, maintain that Defendants stored ranitidine products as provided on the labeling but still stored them under the wrong conditions, Plaintiffs should be prepared to explain how Defendants can be found liable for storing the products in accordance with the labeling. Plaintiffs should be prepared to provide the factual and legal basis for a proposition that, if FDA-approved labeling permits a party to store a drug under certain conditions, a state may nonetheless impose liability for storing the drug under those conditions. To the extent that Plaintiffs maintain that individual Defendants stored ranitidine products under different conditions than those listed on the labeling, Plaintiffs should be prepared to explain how that is an issue for an MDL (which is designed to adjudicate common questions of fact and law) and not an individualized and fact-specific issue. *See* Order Granting Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Granting Distributor Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Denying as Moot Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on State Law Grounds, and Denying as Moot Distributor Defendants' Rule 12 Motion to Dismiss on Various Group-Specific Grounds.

4. Warning the FDA

a. Arguments

Plaintiffs contend that the laws of "a wide swath of states" require drug manufacturers to warn the FDA of potential hazards. DE 2010-1 at 9, 20, 28-29. In those states, the failure of a drug manufacturer to do so is a breach of a duty owed to drug consumers. *Id.* at 31, 36-37. And federal law allows or even requires drug manufacturers to warn the FDA of potential hazards. *Id.* at 9, 20. Consequently, warning the FDA is not impossible, and state claims based on Defendants' failure to warn the FDA of hazards are not pre-empted. *Id.* at 30. Defendants reply that the Supreme Court in *Mensing* rejected the consumers' theory based on failure to ask the FDA for help, and therefore the Court ruled that claims based on failure to warn the FDA are pre-empted. DE 2133 at 6, 13-15.

b. Caselaw on Warning the FDA

In *Mensing*, the consumers brought state-law claims for failure to provide adequate warnings on drugs' labeling. 564 U.S. at 610. The consumers denied that their claims were based on the generic drug manufacturers' failure to ask the FDA for assistance in changing drug labeling. *Id.* at 619. The Supreme Court, applying Minnesota and Louisiana law, explained that "[s]tate law demanded a safer label; it did not instruct the [generic drug manufacturers] to communicate with the FDA about the possibility of a safer label" and concluded that "asking for the FDA's help" was "not a matter of state-law concern." *Id.* at 619, 624.

In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court ruled that the plaintiffs' claims that a company had made fraudulent representations to the FDA during the approval process for a medical device were pre-empted because the federal regulatory scheme tasks the FDA with detecting, deterring, and punishing fraud on the FDA. 531 U.S. 341, 343, 348 (2001) (holding that

"the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law"). The Court reasoned that permitting state law to also police fraud on the FDA would create "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350, 353 (explaining that "this sort of [state] litigation would exert an extraneous pull on the scheme established by Congress"); *see also English*, 496 U.S. at 79 (explaining that state law is pre-empted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (quotation marks omitted)).

The Eleventh Circuit Court of Appeals relied on *Buckman* in *Tsavaris v. Pfizer, Inc.*, where a plaintiff sought to bring a claim that a drug manufacturer had breached its duty under federal law to notify the FDA of scientific studies connecting the use of a drug to the development of cancer. 717 F. App'x 874, 876 (11th Cir. 2017). The court determined that such a claim was pre-empted because the plaintiff was not attempting to enforce a duty of care owed to her, but rather to enforce a federal reporting duty owed to the FDA. *Id.* at 877. "Preemption occurs when the federal government has exclusive power to punish an individual or entity for a violation of a federal statute or regulation." *Id.* (citing *Buckman*, 531 U.S. at 348).

c. Analysis and Conclusion

According to Plaintiffs, *Buckman* and *Tsavaris* are distinguishable because Plaintiffs are asserting a duty owed to consumers under state law, not a duty owed to the FDA or fraud on the FDA; and *Mensing* did not address this claim because the consumers brought their claims for failure to adequately label, not for failure to warn the FDA, and the states at issue did not recognize claims for failure to warn the FDA. DE 2010-1 at 30, 34-37. The Court declines to determine at this juncture whether a state-law claim for failure to warn the FDA, where the duty at issue is one

that is owed to consumers, is pre-empted. This is because Plaintiffs have not pled any claims for failure to warn the FDA. During the Hearing, when asked where in the Master Complaints they raised claims of failure to warn the FDA, Plaintiffs pointed generally to their failure-to-warn counts, such as Counts I and IV of the MPIC. DE 2499 at 60-61. But those counts do not contain allegations that Defendants should have warned the FDA. Plaintiffs' failure-to-warn counts contain allegations relating only to warnings on the labeling of ranitidine products and warnings to consumers through other mediums. *See, e.g.*, MPIC ¶¶ 454-71, 501-16. Should Plaintiffs choose to plead claims for failure to warn the FDA upon repleading, they should do so consistent with the pleading issues that the Court addresses in Section VII.C.2.c. of this Order.

5. Manufacturing Defect

a. Arguments and Allegations

Defendants argue that Plaintiffs' manufacturing-defect counts must be dismissed because "this is not a case where particular batches of ranitidine made by certain defendants may have contained NDMA due to some error in the manufacturing process that caused those batches to depart from the intended design." DE 1582 at 9, 32. Plaintiffs' allegations are that "an inherent flaw in the design of the ranitidine molecule itself created conditions ripe for NDMA formation in *every* unit of ranitidine made by *every* branded manufacturer and *every* generic manufacturer." *Id.* at 9-10, 32. Plaintiffs' manufacturing-defect claims are actually design-defect claims and are pre-empted. *Id.* at 30-32. Further, any manufacturing changes that Plaintiffs propose in the Master Complaints are "major changes" that Defendants could not have made independently without FDA pre-approval, such that claims based on those changes are pre-empted. *Id.* at 33-35.

Plaintiffs do not dispute that a claim would be pre-empted if it were based on an assertion that the drug manufacturer should have made a manufacturing change that could not be made

independently without FDA pre-approval. Plaintiffs maintain, however, that a drug can be both defectively designed and defectively manufactured and that the manufacturing-defect claims they have pled cannot be deemed pre-empted without discovery and further factual development. DE 2010-1 at 37-38.

Plaintiffs allege in the MPIC that ranitidine products "were expected to and did reach Plaintiffs without a substantial change in their anticipated or expected design" "[a]t all relevant times." MPIC ¶¶ 462, 477, 492. Plaintiffs, in fact, include this allegation within their count in the MPIC for strict liability manufacturing defect. *Id.* ¶ 492. Plaintiffs further allege that ranitidine products were "defective with respect to their manufacture" due to failures to follow Current Good Manufacturing Practices and to "implement procedures that would reduce or eliminate NDMA levels in ranitidine-containing products."[9] *Id.* ¶¶ 494, 496(a), (d), 536(a), (c). Plaintiffs make similar allegations in the CCCAC. The CTPPCC does not contain a manufacturing-defect count. Repackager Defendants are not named under the manufacturing-defect counts in the MPIC but are named under the manufacturing-defect counts in the CCCAC.

b. Law on Manufacturing Defects

A product contains a manufacturing defect "when the product departs from its intended design." Restatement (Third) of Torts: Products Liability § 2(a) (Am. L. Inst. 1998). As to the production of drug products, a "major manufacturing change" is a manufacturing change that has "substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug." 21 U.S.C. § 356a(c)(2); *see also* 21 C.F.R. § 314.70(b)(1). This includes a change "in the qualitative or quantitative formulation" of the drug product or a change in the "manufacture of the drug substance that may affect the

[9] The manufacturing-defect counts also contain allegations about testing, expiration dates, and storage conditions. Those issues are separately addressed above.

impurity profile and/or the physical, chemical, or biological properties of the drug substance." 21 U.S.C. § 356a(c)(2)(A); 21 C.F.R. § 314.70(b)(2)(i), (iv). A drug product that is made with a major manufacturing change may be distributed only upon the submission of a Prior Approval Supplement to the FDA and FDA approval. 21 U.S.C. § 356a(c)(1); *see also* 21 C.F.R. § 314.70(b).

c. Analysis and Conclusion

Plaintiffs have not pled a plausible manufacturing-defect claim. *See Twombly*, 550 U.S. at 555, 570 (requiring a complaint to provide sufficient factual allegations to "state a claim to relief that is plausible on its face" and to "raise a right to relief above the speculative level"). Not only do Plaintiffs allege within a manufacturing-defect count itself that ranitidine products reached consumers without a substantial change to their design, but Plaintiffs also fail to plead any specific facts such as the identification of how any particular batch of ranitidine products departed from their intended design or of any particular manufacturing processes or procedures that should have been but were not followed. *See Iqbal*, 556 U.S. at 678 (stating that a complaint must offer more than labels, conclusory statements, and naked assertions devoid of factual enhancement to plead a claim upon which relief can be granted). The Court is unprepared to conclude, as Defendants maintain, that Plaintiffs are wholly unable to plausibly plead a manufacturing-defect claim. *See* DE 1582 at 30. And in this posture of the pleadings, the Court is unable to evaluate Defendants' contention that the manufacturing-defect claims are pre-empted. Plaintiffs' manufacturing-defect counts against Generic Manufacturer Defendants are dismissed without prejudice and with leave to amend.

Plaintiffs do not separately address the manufacturing-defect counts against Repackager Defendants in the CCCAC. Repackager Defendants are not alleged to have manufactured

ranitidine products.[10] *See* CCCAC ¶ 416 (defining Repackager Defendants as entities that repackaged ranitidine products into different containers and changed "the content on an original manufacturer's label to note the drug [was] distributed or sold under the relabeler's own name," "without manipulating, changing, or affecting the composition or formulation of the drug"). To the extent that Plaintiffs seek to hold Repackager Defendants liable for any manufacturing defects under an absolute-liability theory, absolute liability is addressed briefly in Section VII.C.7. of this Order and more expansively in the Order Granting Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Granting Distributor Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Denying as Moot Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on State Law Grounds, and Denying as Moot Distributor Defendants' Rule 12 Motion to Dismiss on Various Group-Specific Grounds. For the reasons given in that Order, Plaintiffs' manufacturing-defect counts against Repackager Defendants are dismissed with prejudice.

6. MMWA Claims

a. Arguments and Allegations

Defendants assert that the counts for violation of the MMWA in the CCCAC and CTPPCC must be dismissed because those counts require a valid state-law warranty claim to serve as an "anchor," and none of Plaintiffs' state-law warranty claims are valid because they are pre-empted. DE 1582 at 10, 39. In addition, the MMWA does not apply to FDA-regulated product labeling. *Id.* at 10, 39-40.

Plaintiffs do not dispute that their claims under the MMWA require a valid state-law warranty claim. *See* DE 2499 at 63-64 (argument of Plaintiffs that they have valid

[10] The Court notes again, however, that some of the parties categorized as Generic Manufacturer Defendants are also categorized as Repackager Defendants. *See, e.g.*, CCCAC ¶¶ 280, 288.

express-warranty and implied-warranty claims to serve as a MMWA "anchor"). Plaintiffs argue, however, that their state-law warranty claims are valid because they are not pre-empted. DE 2010-1 at 40. If the Court concludes at this stage that the MMWA does not apply to written warranties arising from FDA-regulated product labeling, Plaintiffs still can pursue their claims for breach of implied warranties under the MMWA. *Id.* at 40-41.

Plaintiffs allege in their MMWA counts that Defendants expressly warranted that ranitidine products "were safe for human consumption and fit to be used for their intended purpose" and that Defendants impliedly warranted that the products "were of merchantable quality and safe and fit for their intended use." *See, e.g.*, CCCAC ¶¶ 810, 814; CTPPCC ¶¶ 595, 599. Defendants breached these warranties because ranitidine products were dangerous in that they contained cancer-causing levels of NDMA. *See, e.g.*, CCCAC ¶¶ 811, 813, 817; CTPPCC ¶¶ 596, 598, 602.

b. The MMWA

The MMWA provides a private cause of action for "a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation . . . under a written warranty, implied warranty, or service contract." 15 U.S.C. § 2310(d)(1). A "supplier" is "any person engaged in the business of making a consumer product directly or indirectly available to consumers," and a "warrantor" is "any supplier or other person who gives or offers to give a written warranty or who is or may be obligated under an implied warranty." *Id.* § 2301(4), (5). The MMWA defines the phrase "written warranty" as

> (A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time, or
>
> (B) any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take other remedial action with

> respect to such product in the event that such product fails to meet the specifications set forth in the undertaking,
>
> which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.

Id. § 2301(6). The phrase "implied warranty" means "an implied warranty arising under State law . . . in connection with the sale by a supplier of a consumer product." *Id.* § 2301(7); *see Barabino v. Dan Gamel, Inc.*, No. 2:04-cv-2359-MCE-PAN, 2006 WL 2083257, at *4 (E.D. Cal. July 25, 2006) (explaining that "courts must look to the relevant state law to determine the meaning and creation of any implied warranty" when applying the MMWA).

A plaintiff's claim under the MMWA is viable only if the plaintiff also has stated a valid breach-of-warranty claim under state law. *See Cardenas v. Toyota Motor Corp.*, 418 F. Supp. 3d 1090, 1110-11 (S.D. Fla. 2019) (explaining that, "[t]o state a claim under the Magnuson-Moss Warranty Act, . . . a plaintiff must also state a valid breach of warranty claim"); *Melton v. Century Arms, Inc.*, 243 F. Supp. 3d 1290, 1304 (S.D. Fla. 2017) (explaining that "a Magnuson-Moss Warranty Act claim only exists if a valid breach of warranty claim is also stated").

The MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." 15 U.S.C. § 2311(d). "If only a portion of a written warranty is so governed by Federal law, the remaining potion shall be subject to" the MMWA. *Id.* Applying § 2311(d), federal courts have held that the MMWA is inapplicable to both express-warranty and implied-warranty claims for products with FDA-regulated labeling. *See, e.g., Hernandez v. Johnson & Johnson Consumer Inc.*, No. 3:19-cv-15679-BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (concluding that the MMWA "is inapplicable to any alleged express or implied warranty claims on the labeling of" pain relievers); *Dopico v. IMS Trading Corp.*, No. 3:14-cv-1874-BRM-DEA, 2018 WL 4489677, at *6 (D.N.J. Sept. 18, 2018) (concluding that

the MMWA "is inapplicable to any alleged express or implied warranty claims on the labeling of" FDA-regulated dog treats); *Jasper v. MusclePharm Corp.*, No. 14-cv-02881-CMA-MJW, 2015 WL 2375945, at *1, 5-6 (D. Colo. May 15, 2015) (adopting a Report and Recommendation to dismiss a MMWA claim under § 2311(d) where the plaintiff had brought express-warranty and implied-warranty claims related to weight-loss supplements and citing multiple cases as reaching the conclusion that "the label of the product at issue is 'governed' under the FDCA, and therefore the Magnuson-Moss Warranty Act is 'inapplicable'").[11]

c. Analysis and Conclusion

As discussed in Section VII.C.1.e. of this Order, the Court is dismissing all counts against Defendants, including the counts for breach of express and implied warranties. The Court therefore dismisses the MMWA counts, as a MMWA claim requires a valid breach-of-warranty claim. *See Cardenas*, 418 F. Supp. 3d at 1110-11; *Melton*, 243 F. Supp. 3d at 1304.

Should Plaintiffs replead any express-warranty or implied-warranty claims and replead MMWA claims, the MMWA is inapplicable to warranty claims based on language on drug labeling that the FDA governs and that falls within the definition of "written warranty." *See* 15 U.S.C. § 2311(d) (providing that the MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law"). To the extent that Plaintiffs maintain that they can pursue written warranty claims under the MMWA based on any language that the FDA does not govern, they have failed to plead a plausible claim under the MMWA

[11] Plaintiffs cite a single case to support their argument that they can pursue claims for breach of implied warranties under the MMWA. *See* DE 2010-1 at 41. That case, *Forcellati v. Hyland's Inc.*, concluded that the plaintiffs had not identified language on the labeling of homeopathic remedies that fell within the definition of "written warranty" under the MMWA, but that the plaintiffs were entitled to a trial on their claim of breach of implied warranty under the MMWA. No. CV 12-1983-GHK, 2015 WL 9685557, at *6 (C.D. Cal. Jan. 12, 2015). *Forcellati* is distinguishable because the FDA does not approve the labeling for homeopathic remedies. Plaintiffs have not cited any authority to support a departure from caselaw specific to the drug context that has held that the MMWA is inapplicable to both express-warranty and implied-warranty claims. *See Hernandez*, 2020 WL 2537633, at *5.

because they have not specified the relevant language that they assert meets the MMWA's definition of "written warranty." *See id.* (explaining that, "[i]f only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter"); *see also id.* § 2301(6) (defining the phrase "written warranty"); *Viggiano v. Hansen Nat. Corp.*, 944 F. Supp. 2d 877, 898 (C.D. Cal. 2013) (dismissing a MMWA claim because the challenged language on product labeling did not create a written warranty within the definition in the MMWA). To the extent that Plaintiffs still maintain that they can pursue implied-warranty claims under the MMWA, they should be prepared to explain whether their implied-warranty claims arise from anything other than the drug labeling. The MMWA count in the CCCAC, Count 3, against Defendants and the MMWA count in the CTPPCC, Count 4, against Generic Manufacturer Defendants are dismissed without prejudice and with leave to amend.

7. Absolute Liability

In their Opposition to the Motion to Dismiss, Plaintiffs "incorporate by reference the Retailer, Pharmacy, and Distributor opposition, which refutes the Repackager Defendants' arguments." DE 2010-1 at 41. By that statement, the Court presumes that Plaintiffs mean to incorporate their arguments about absolute liability in their Opposition to Distributor, Retailer, and Pharmacy Defendants' Rule 12 Motions to Dismiss on Preemption Grounds. *See* DE 1977 at 12-17. Defendants reply that Plaintiffs have failed to show that any state has adopted an absolute liability framework for repackagers. DE 2133 at 7-8, 22. Defendants further argue that, if a state were to adopt such a framework, the state's law would directly conflict with federal law. *Id.* at 22.

The Court's discussion and analysis of absolute liability is included within the Order Granting Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Granting Distributor Defendants' Rule 12 Motion to Dismiss on the Ground of

Preemption, Denying as Moot Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on State Law Grounds, and Denying as Moot Distributor Defendants' Rule 12 Motion to Dismiss on Various Group-Specific Grounds. For the reasons given in that Order, any claims against Repackager Defendants that rely on absolute liability are dismissed with prejudice.

8. Derivative Counts

Counts XIII, XIV, and XV of the MPIC are claims for loss of consortium, damages to be paid to the estates of deceased ranitidine-product consumers, and wrongful death. MPIC ¶¶ 637-56. Defendants refer to these three counts as "derivative" claims and argue that these claims must be dismissed if all of the other claims against them are dismissed. DE 1582 at 37-38. Plaintiffs do not dispute that the derivative claims must be dismissed if no other claims remain against Defendants, but Plaintiffs assert again that they can proceed with all of their claims against Defendants. DE 2010-1 at 39; *see In re Darvocet*, 756 F.3d at 936 (affirming a district court's dismissal of "derivative claims for wrongful death, survivorship, unjust enrichment, loss of consortium, and punitive damages" when the district court had dismissed all "underlying claims" because the derivative claims "stand or fall with the underlying claims on which they rest"). Because the Court is dismissing all underlying claims against Defendants for the reasons given herein, the derivative claims raised against Defendants in Counts XIII, XIV, and XV of the MPIC are dismissed without prejudice.

9. Express Pre-emption Under 21 U.S.C. § 379r

Defendants' Motion to Dismiss incorporates by reference the arguments about express pre-emption that Brand-Name Manufacturer Defendants make in their motion to dismiss based on pre-emption. DE 1582 at 38-39; *see* DE 1580. In that motion to dismiss, Brand-Name Manufacturer Defendants contend that 21 U.S.C. § 379r prohibits Plaintiffs from obtaining

damages in the form of refunds for the purchase of OTC ranitidine products. DE 1580 at 7, 14-22; *see* 21 U.S.C. § 379r(a) (providing that "no State or political subdivision of a State may establish or continue in effect any requirement . . . that is different or in addition to, or that is otherwise not identical with, a requirement under this chapter"). The Court will address § 379r in a forthcoming Order on Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law.

VIII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that Defendant Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption [DE 1582] is **GRANTED.**

1. Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are **DISMISSED WITH PREJUDICE** consistent with this Order. Because all of Plaintiffs' counts against Defendants in the Master Complaints incorporate such allegations, all counts against Defendants are **DISMISSED**.

2. Plaintiffs' claims against Repackager Defendants that rely on absolute liability are **DISMISSED WITH PREJUDICE** consistent with this Order.

3. Plaintiffs are granted leave to replead claims against Defendants based on expiration dates, testing, storage and transportation conditions, warning the FDA, manufacturing defects, and the MMWA, as well as to replead their derivative counts, consistent with this Order.

4. Under Pretrial Order # 36, Plaintiffs' repled Master Complaints are due 30 days after the Court issues its Order on Article III standing. DE 1346 at 4. The Court **AMENDS** that requirement in Pretrial Order # 36. Plaintiffs' repled Master Complaints are due 30 days after the

Court issues its forthcoming Order on Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. DE 1580. All other requirements in Pretrial Order # 36 remain in place.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 31st day of December, 2020.

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is **BLANK ROME LLP**, 2029 Century Park East, 6th Floor, Los Angeles, California 90067.

On **February 19, 2021**, I served the foregoing document(s): DEFENDANT APOTEX CORP.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF ITS DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT on the interested parties in this action addressed and sent as follows:

SEE ATTACHED SERVICE LIST

☒ **BY ENVELOPE:** by placing ☐ the original ☒ a true copy thereof enclosed in sealed envelope(s) addressed as indicated and delivering such envelope(s):

☒ **BY MAIL:** I caused such envelope(s) to be deposited in the mail at Los Angeles, California with postage thereon fully prepaid to the office or home of the addressee(s) as indicated. I am "readily familiar" with this firm's practice of collection and processing documents for mailing. It is deposited with the U.S. Postal Service on that same day, with postage fully prepaid, in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in affidavit.

☐ **BY FEDEX:** I caused such envelope(s) to be deposited in a box or other facility regularly maintained by FedEx, an express service carrier, or delivered to a courier or driver authorized by said express service carrier to receive documents in an envelope designated by the said express service carrier, addressed as indicated, with delivery fees paid or provided for, to be transmitted by FedEx.

☒ **BY ELECTRONIC SERVICE (EMAIL):** Pursuant to Temporary Emergency Rule #12 related to electronic service of documents via email enacted by the California Judicial Counsel due to the National Emergency and public health orders in California related to the coronavirus and COVID-19 pandemic, I caused the document(s) listed above to be transmitted to the person(s) at the e-mail address(es) as indicated. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the transmission was incomplete or unsuccessful.

☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on **February 19, 2021**, at Los Angeles, California.

Michelle Grams

SERVICE LIST

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Mark N. Todzo Joseph Mann LEXINGTON LAW GROUP 503 Divisadero Street San Francisco, CA 94117 Telephone: (415) 913-7800 Facsimile: (415) 759-4112 Email: mtodzo@lexlawgroup.com; jmann@lexlawgroup.com;	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Dennis Raglin Danielle Vallone STEPTOE & JOHNSON LLP 633 West Fifth St., Suite 1900 Los Angeles, CA 90071 Email: draglin@steptoe.com; dvallone@steptoe.com	Attorneys for Defendant PERRIGO COMPANY
Jeffrey B. Margulies Lauren A. Shoor Andy Guo NORTON ROSE FULBRIGHT US LLP 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Telephone: (213) 892-9200 Facsimile: (213) 892-9494 Email: jeff.margulies@nortonrosefulbright.com; lauren.shoor@nortonrosefulbright.com; andy.guo@nortonrosefulbright.com	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers LEWIS BRISBOIS BISGAARD & SMITH LLP 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: (415) 438-6615 Fax: (415) 434-0882 Email: Paul.desrochers@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.
Walter (Pete) H. Swayze, III Megan E. Grossman LEWIS BRISBOIS BISGAARD & SMITH LLP Philadelphia, PA 550 E. Swedesford Road, Suite 270 Wayne, PA 19087 Tel: (215) 977-4100 Fax: (215) 977-4101 Email: Pete.Swayze@lewisbrisbois.com; Megan.Grossman@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Brian Ledger GORDON REESE SCULLY MANSUKHANI LLP 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: (619) 696-6700 Fax: (619) 696-7124 Email: bledger@gordonrees.com	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas Greg Sperla DLA PIPER 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: (916) 930-3200 Fax: (916) 930-3201 Email: George.gigounas@dlapiper.com; Greg.sperla@dlapiper.com	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner Deepi K. Miller GREENBERG TRAURIG, LLP 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: (916) 442-1111 Fax: (916) 448-1709 Email: wagnerw@gtlaw.com; millerde@gtlaw.com	Attorneys for Defendant 7-ELEVEN, INC.
Trenton H. Norris ARNOLD & PORTER KAYE SCHOLER LLP 10th Floor Three Embarcadero Center San Francisco, CA 94111-4024 Tel: (415) 471-3100 Fax: (415) 471-3400 Email: Trent.Norris@arnoldporter.com	
Linda E. Maichl John R. Ipsaro Megan B. Gramke ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202-2409 Tel: (513) 698-5000 Fax: (513) 698-5013 Email: lmaichl@ulmer.com; jipsaro@ulmer.com; mgramke@ulmer.com	Attorneys for Defendants DR. REDDY'S LABORATORIES LOUISIANA, LLC and DR. REDDY'S LABORATORIES, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Richard M. Barnes
Sean Gugerty
GOODELL, DEVRIES, LEECH & DANN, LLP
One South Street, 20th Floor
Baltimore, MD 21202
Tel: 410-783-4000
Fax: 410-783-4040
Email: rmb@gdldlaw.com;
sgugerty@gdldlaw.com

Attorneys for Defendant
PERRIGO COMPANY

Exhibit 9

BLANK ROME LLP
Cheryl S. Chang (SBN 237098)
Chang@BlankRome.com
Erika R. Schulz (SBN 313289)
ESchulz@BlankRome.com
2029 Century Park East, 6th Floor
Los Angeles, CA 90067
Telephone: 424.239.3400
Facsimile: 424.239.3434

Attorneys for Defendant,
APOTEX CORP.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et. al.*,

Defendants.

Case No. RG-20-054985

[*Assigned to Honorable Winifred Y. Smith, Dept. 21*]

[PROPOSED] ORDER SUSTAINING DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Date: April 30, 2021
Time: 10:00 a.m.
Dept: 21

Complaint Filed: February 19, 2020
SAC Filed: January 4, 2021
Trial Date: None Set

Hearing Reservation ID #R2240282

[*Filed concurrently with Demurrer, Declaration of Erika Schulz, and Request for Judicial Notice*]

On April 30, 2021, at 10:00 a.m., in Department 21 of the above-entitled Court, located at 1221 Oak Street, Oakland, CA 94612, defendant Apotex Corp. ("Apotex")'s demurrer ("Demurrer") to the second amended complaint ("SAC") filed by plaintiff Center for Environmental Health ("CEH") came on regularly for hearing before this Court, the Honorable Winifred Smith presiding. Appearances were made as noted on the record.

The Court, having considered all papers submitted, the arguments of counsel, and good cause appearing therefore, it is hereby ORDERED as follows:

1) Apotex's Demurrer is SUSTAINED without leave to amend;

2) CEH's SAC is DISMISSED with prejudice;

3) Apotex shall prepare a proposed judgment; and

4) Apotex shall give notice of this ruling.

IT IS SO ORDERED.

Dated: _____

_____
Honorable Winifred Y. Smith
Judge of the Superior Court of California for the County of Alameda

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is **BLANK ROME LLP**, 2029 Century Park East, 6th Floor, Los Angeles, California 90067.

On **February 19, 2021**, I served the foregoing document(s): [PROPOSED] ORDER SUSTAINING DEFENDANT APOTEX CORP.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT on the interested parties in this action addressed and sent as follows:

SEE ATTACHED SERVICE LIST

☒ **BY ENVELOPE:** by placing ☐ the original ☒ a true copy thereof enclosed in sealed envelope(s) addressed as indicated and delivering such envelope(s):

☒ **BY MAIL:** I caused such envelope(s) to be deposited in the mail at Los Angeles, California with postage thereon fully prepaid to the office or home of the addressee(s) as indicated. I am "readily familiar" with this firm's practice of collection and processing documents for mailing. It is deposited with the U.S. Postal Service on that same day, with postage fully prepaid, in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in affidavit.

☐ **BY FEDEX:** I caused such envelope(s) to be deposited in a box or other facility regularly maintained by FedEx, an express service carrier, or delivered to a courier or driver authorized by said express service carrier to receive documents in an envelope designated by the said express service carrier, addressed as indicated, with delivery fees paid or provided for, to be transmitted by FedEx.

☒ **BY ELECTRONIC SERVICE (EMAIL):** Pursuant to Temporary Emergency Rule #12 related to electronic service of documents via email enacted by the California Judicial Counsel due to the National Emergency and public health orders in California related to the coronavirus and COVID-19 pandemic, I caused the document(s) listed above to be transmitted to the person(s) at the e-mail address(es) as indicated. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the transmission was incomplete or unsuccessful.

☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on **February 19, 2021**, at Los Angeles, California.

Michelle Grams

SERVICE LIST

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Mark N. Todzo Joseph Mann LEXINGTON LAW GROUP 503 Divisadero Street San Francisco, CA 94117 Telephone: (415) 913-7800 Facsimile: (415) 759-4112 Email: mtodzo@lexlawgroup.com; jmann@lexlawgroup.com;	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Dennis Raglin Danielle Vallone STEPTOE & JOHNSON LLP 633 West Fifth St., Suite 1900 Los Angeles, CA 90071 Email: draglin@steptoe.com; dvallone@steptoe.com	Attorneys for Defendant PERRIGO COMPANY
Jeffrey B. Margulies Lauren A. Shoor Andy Guo NORTON ROSE FULBRIGHT US LLP 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Telephone: (213) 892-9200 Facsimile: (213) 892-9494 Email: jeff.margulies@nortonrosefulbright.com; lauren.shoor@nortonrosefulbright.com; andy.guo@nortonrosefulbright.com	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers LEWIS BRISBOIS BISGAARD & SMITH LLP 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: (415) 438-6615 Fax: (415) 434-0882 Email: Paul.desrochers@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.
Walter (Pete) H. Swayze, III Megan E. Grossman LEWIS BRISBOIS BISGAARD & SMITH LLP Philadelphia, PA 550 E. Swedesford Road, Suite 270 Wayne, PA 19087 Tel: (215) 977-4100 Fax: (215) 977-4101 Email: Pete.Swayze@lewisbrisbois.com; Megan.Grossman@lewisbrisbois.com	Attorneys for Defendant GRANULES USA, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Brian Ledger GORDON REESE SCULLY MANSUKHANI LLP 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: (619) 696-6700 Fax: (619) 696-7124 Email: bledger@gordonrees.com	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas Greg Sperla DLA PIPER 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: (916) 930-3200 Fax: (916) 930-3201 Email: George.gigounas@dlapiper.com; Greg.sperla@dlapiper.com	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner Deepi K. Miller GREENBERG TRAURIG, LLP 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: (916) 442-1111 Fax: (916) 448-1709 Email: wagnerw@gtlaw.com; millerde@gtlaw.com	Attorneys for Defendant 7-ELEVEN, INC.
Trenton H. Norris ARNOLD & PORTER KAYE SCHOLER LLP 10th Floor Three Embarcadero Center San Francisco, CA 94111-4024 Tel: (415) 471-3100 Fax: (415) 471-3400 Email: Trent.Norris@arnoldporter.com	
Linda E. Maichl John R. Ipsaro Megan B. Gramke ULMER & BERNE LLP 600 Vine Street, Suite 2800 Cincinnati, Ohio 45202-2409 Tel: (513) 698-5000 Fax: (513) 698-5013 Email: lmaichl@ulmer.com; jipsaro@ulmer.com; mgramke@ulmer.com	Attorneys for Defendants DR. REDDY'S LABORATORIES LOUISIANA, LLC and DR. REDDY'S LABORATORIES, INC.

SERVICE LIST (Continued)

Center for Environmental Health v. Perrigo Company, et al.
Alameda Case No. RG 20-054985

Richard M. Barnes
Sean Gugerty
GOODELL, DEVRIES, LEECH & DANN, LLP
One South Street, 20th Floor
Baltimore, MD 21202
Tel: 410-783-4000
Fax: 410-783-4040
Email: rmb@gdldlaw.com;
sgugerty@gdldlaw.com

Attorneys for Defendant
PERRIGO COMPANY

Exhibit 10

Deepi Miller (SBN 272497)
millerde@gtlaw.com
Willis M. Wagner (SBN 310900)
wagnerw@gtlaw.com
GREENBERG TRAURIG, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814-3938
Telephone: (916) 442-1111
Facsimile: (916) 448-1709

Trenton H. Norris (SBN 164781)
trent.norris@arnoldporter
Vanessa C. Adriance (SBN 24746)
vanessa.adriance@arnoldporter.com
ARNOLD & PORTER
Three Embarcadero Center, 10th Floor
San Francisco, CA 94111-4075
Telephone: (415) 471-3303
Facsimile: (415) 471-3400

Attorneys for Defendant
7-ELEVEN, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG 20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

NOTICE OF DEFENDANT 7-ELEVEN, INC.'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[*Filed concurrently with Joint Memorandum of Points and Authorities; Joint Request for Judicial Notice; Declaration of Lauren A. Shoor and Proposed Order*]

RESERVATION NO.: R-2240281

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

TO THE COURT, ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on **April 30, 2021**, at 10:00 a.m., or as soon as the matter can be heard, in Department 21 of the Alameda County Superior Court, located at 1221 Oak Street, Oakland, California, Defendant 7-Eleven, Inc. ("7-Eleven") will demur to Plaintiffs' Second Amended Complaint pursuant to California Code of Civil Procedure, Sections 430.10(e) and 430.30, on the grounds that it fails to state a cause of action against 7-Eleven.

7-Eleven's Demurrer will be based on this Notice of Demurrer and Demurrer, the accompanying Joint Memorandums of Points and Authorities by the Retail Defendants and the Generic Defendants, the Joint Request for Judicial Notice, and the Declaration of Lauren A. Shoor, as well as such other evidence the Court may consider.

DATED: February 19, 2021

GREENBERG TRAURIG, LLP

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____
Will Wagner
Attorneys for Defendant
7-ELEVEN, INC.

DATED: February 19, 2021

ARNOLD & PORTER

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____
Trenton H. Norris
Vanessa C. Adriance
Attorneys for Defendant
7-ELEVEN, INC.

GENERAL DEMURRER

The Second Amended Complaint against 7-Eleven fails to state facts sufficient to constitute a case of actions pursuant to Code of Civil Procedure Sections 430.10(e) and 430.30.

Demurrer to Plaintiffs' First Cause of Action for Injunctive Relief and Civil Penalties

1. Plaintiff's First Cause of Action alleging a violation of Health & Safety Code Section 25249.6, *et seq*, does not contain facts sufficient to state a cause of action against 7-Eleven because Plaintiff's claim that 7-Eleven failed to provide a Proposition 65 warning for its over-the-counter drug ranitidine in violation of this section is preempted by federal law. (California Code of Civil Procedure Sections 430.10(e), 430.)

WHEREFORE, 7-Eleven prays that this demurrer be sustained without leave to amend, that Plaintiff take nothing by its Second Amended Complaint, and that 7-Eleven be awarded judgment for its costs and all other proper relief.

DATED: February 19, 2021

GREENBERG TRAURIG, LLP

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____
Will Wagner
Attorneys for Defendant
7-ELEVEN, INC.

DATED: February 19, 2021

ARNOLD & PORTER

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____
Trenton H. Norris
Vanessa C. Adriance
Attorneys for Defendant
7-ELEVEN, INC.

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **NOTICE OF DEFENDANT 7-ELEVEN, INC.'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents.
Note: Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com ARNOLD & PORTER Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Telephone: (415) 471-3303 Facsimile: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 11

Jeffrey B. Margulies (SBN 126002)
jeff.margulies@nortonrosefulbright.com
Lauren A. Shoor (SBN 280788)
lauren.shoor@nortonrosefulbright.com
NORTON ROSE FULBRIGHT US LLP
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Attorneys for Defendant
TARGET CORPORATION

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[*Filed concurrently with Notice of Demurrer; Joint Memorandum of Points and Authorities; Joint Request for Judicial Notice and Proposed Order*]

RESERVATION NO.: R-2240281

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

I, Lauren A. Shoor, declare as follows:

1. I am an attorney duly admitted to practice before this Court and all courts in the State of California and am a senior associate with the law firm of Norton Rose Fulbright US LLP, attorneys of record for defendant Target Corporation. I submit this declaration in accordance with California Code of Civil Procedure Section 430.41(a). I have personal knowledge of the following and can and do competently testify thereto.

2. On February 12, 2021, I participated in a telephone conference with counsel for defendant 7-Eleven, Inc. and plaintiff Center for Environmental Health ("CEH") to meet and confer on Target and 7-Eleven's (collectively "Defendants") contemplated joint demurrer to CEH's Second Amended Complaint which asserts a single cause of action against Defendants for alleged violation of Health & Safety Code § 25249.6, Proposition 65.

3. We discussed the legal support for Defendants' contemplated demurrer on the grounds that CEH's claim is preempted by federal law.

4. On February 12, 2021, following our telephone conference, counsel for 7-Eleven and I emailed counsel for CEH the citations to the legal authorities discussed during our telephone conference.

5. Counsel for CEH stated on the call that he would follow up by email if he believed the objections raised in the demurrer could be resolved, and CEH's counsel did not respond to our emails to indicate that the objections raised in the demurrer could be resolved.

I declare under penalty of perjury of the laws of the State of California that the foregoing is true and correct. Executed this 18th day of February, 2020, at Los Angeles, California.

Lauren A. Shoor

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents.
Note: Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fac: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 12

Deepi Miller (SBN 272497)
millerde@gtlaw.com
Will Wagner (SBN 310900)
wagnerw@gtlaw.com
GREENBERG TRAUIG, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814
Telephone: 916-442-1111
Facsimile: 916-448-1709

Attorneys for Defendant
7-ELEVEN, INC.

Trenton H. Norris (SBN 164781)
trent.norris@arnoldporter
Vanessa C. Adriance (SBN 24746)
vanessa.adriance@arnoldporter.com
ARNOLD & PORTER
Three Embarcadero Center, 10th Floor
San Francisco, CA 94111-4075
Telephone: (415) 471-3303
Facsimile: (415) 471-3400

Attorneys for Defendant
7-ELEVEN, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG 20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

[PROPOSED] ORDER SUSTAINING DEFENDANT 7-ELEVEN, INC.'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND

[*Filed concurrently with Notice of Demurrer and Demurrer; Joint Memorandums of Points and Authorities; Joint Request for Judicial Notice and Declaration of Counsel*]

RESERVATION NO.: R-2240281

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

The Court, having considered the Demurrer of Defendant 7-Eleven, Inc. ("7-Eleven"), the papers filed in response thereto, all other argument and the record in this case, and for good cause shown:

1. SUSTAINS the Demurrer;

2. Finds Plaintiff's claim against 7-Eleven, reflected in the First Cause of Action alleging a violation of Health & Safety Code Section 25249.6, *et seq*, fails to state facts sufficient to constitute a case of actions pursuant to Code of Civil Procedure Sections 430.10(e) and 430.30;

3. Orders the Second Amended Complaint DISMISSED WITH PREJUDICE from this action; and

4. Orders judgment to be entered in favor of 7-Eleven.

IT IS SO ORDERED.

DATED:

_____

Hon. Winifred Y. Smith
County of Alameda Superior Court

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021** I served the following listed document(s), by method indicated below, on the parties in this action: **[PROPOSED] ORDER SUSTAINING DEFENDANT 7-ELEVEN, INC.'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents. **Note:** Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fax: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 13

Jeffrey B. Margulies (SBN 126002)
jeff.margulies@nortonrosefulbright.com
Lauren A. Shoor (SBN 280788)
lauren.shoor@nortonrosefulbright.com
NORTON ROSE FULBRIGHT US LLP
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Attorneys for Defendant
TARGET CORPORATION

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

NOTICE OF DEFENDANT TARGET CORPORATION'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[*Filed concurrently with Joint Memorandum of Points and Authorities; Joint Request for Judicial Notice; Declaration of Lauren A. Shoor and Proposed Order*]

RESERVATION NO.: R-2242040

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

TO THE COURT, ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on **April 30, 2021**, at 10:00 a.m., or as soon as the matter can be heard, in Department 21 of the Alameda County Superior Court, located at 1221 Oak Street, Oakland, California, Defendant Target Corporation ("Target") will demur to Plaintiffs' Second Amended Complaint pursuant to California Code of Civil Procedure, Sections 430.10(e) and 430.30, on the grounds that it fails to state a cause of action against Target.

Target's Demurrer will be based on this Notice of Demurrer and Demurrer, the accompanying Joint Memorandums of Points and Authorities by the Retail Defendants and the Generic Defendants, the Joint Request for Judicial Notice, and the Declarations of Lauren A. Shoor, as well as such other evidence the Court may consider.

DATED: February 19, 2021

NORTON ROSE FULBRIGHT US LLP

"SIGNED ON BEHALF OF WITH PERMISSION"

By: _____

Jeffery Margulies
Lauren Shoor
Attorneys for Defendant
TARGET CORPORATION

GENERAL DEMURRER

The Second Amended Complaint against Target fails to state facts sufficient to constitute a case of actions pursuant to Code of Civil Procedure Sections 430.10(e) and 430.30.

Demurrer to Plaintiffs' First Cause of Action for Injunctive Relief and Civil Penalties

1. Plaintiff's First Cause of Action alleging a violation of Health & Safety Code Section 25249.6, *et seq*, does not contain facts sufficient to state a cause of action against Target because Plaintiff's claim that Target failed to provide a Proposition 65 warning for its over-the-counter drug ranitidine in violation of this section is preempted by federal law. (California Code of Civil Procedure Sections 430.10(e), 430.)

WHEREFORE, Target prays that this demurrer be sustained without leave to amend, that Plaintiff take nothing by its Second Amended Complaint, and that Target be awarded judgment for its costs and all other proper relief.

DATED: February 19, 2021

NORTON ROSE FULBRIGHT US LLP

"SIGNED ON BEHALF OF WITH PERMISSION"

By: _____

Jeffery Margulies
Lauren Shoor
Attorneys for Defendant
TARGET CORPORATION

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **NOTICE OF DEFENDANT TARGET CORPORATION'S DEMURRER AND DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents.
Note: Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. george.gigounas@dlapiper.com Greg Sperla, Esq. greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: 415.471.3303 Fax: 415. 471.3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 14

Jeffery B. Margulies (SBN 126002)
jeff.margulies@nortonrosefulbright.com
Lauren A. Shoor (SBN 280788)
lauren.shoor@nortonrosefulbright.com
NORTON ROSE FULBRIGHT US LLP
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Attorneys for Defendant
TARGET CORPORATION

Trenton H. Norris (SBN 164781)
trent.norris@arnoldporter
Vanessa C. Adriance (SBN 24746)
vanessa.adriance@arnoldporter.com
ARNOLD & PORTER
Three Embarcadero Center, 10th Floor
San Francisco, CA 94111-4075
Telephone: (415) 471-3303
Facsimile: (415) 471-3400

Attorneys for Defendant
7-ELEVEN, INC.

Will Wagner (SBN 310900)
wagnerw@gtlaw.com
GREENBERG TRAUIG, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814
Telephone: 916-442-1111
Facsimile: 916-448-1709

Attorneys for Defendant
7-ELEVEN, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, et. al.,

Defendants.

Case No. RG20054985

Assigned for All Purposes to Honorable Winifred Y. Smith - Dept. 21

DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[Filed concurrently with Notices of Demurrer; Declaration of Lauren A. Shoor; Request for Judicial Notice and Proposed Orders]

RESERVATION NO.: R-2242040

Hearing Date	**April 30. 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19. 2020
SAC Filed:	January 4. 2021
Trial Date:	None Set

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

STATE STATUTES

OTHER AUTHORITIES

REGULATIONS

I. INTRODUCTION

Plaintiff's one-count Proposition 65 action is federally preempted because it seeks to hold retailers of generic ranitidine medications liable under state law for marketing and selling products with Food & Drug Administration ("FDA") mandated labeling that allegedly failed to warn consumers of exposure to a Proposition 65-listed chemical in ranitidine. Proposition 65 is a unique law to California, potentially requiring cancer and/or reproductive toxicity warnings with products when consumers are exposed to any of approximately 900 chemicals. However, by its own terms, Proposition 65 "shall not apply to . . . [a]n exposure for which federal law governs warning in a manner that preempts state authority." Cal. Health & Safety Code § 25249.10(a). Under well-settled and consistent federal precedent, federal law governs the warnings provided for drugs in a manner that entirely preempts and bars retailers and others in the supply chain that do not hold FDA-approved applications for the drug products that they merely distribute or sell from changing the labels or otherwise providing supplemental warnings to consumers different than those already approved by the FDA.

California courts must follow United States Supreme Court precedents on the existence, nature, and scope of federal preemption. The United States Supreme Court's *Mensing* and *Bartlett* decisions[1] hold that federal law governs all warnings for generic drugs and preempts any state-law duties to provide new or different warnings. The underlying principle behind both decisions is that when a party cannot **independently** craft new or different warnings about a drug product without running afoul of federal law, and a plaintiff claims that state law requires additional or different warnings, the state law claim is preempted and must be dismissed.

Under this principle, Proposition 65 warnings for retailers of generic drug products are federally preempted. The Federal Food, Drug, and Cosmetic Act ("FDCA") and its enabling regulations provide that, for FDA-approved drugs, only the holder of the FDA-approved application may independently change the drug's labeling (in certain circumstances) or apply to FDA for permission to make other changes to drug labeling or design. Since *Mensing* and

[1] *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604; *Mut. Pharm. Co. v. Bartlett* (2013) 570 U.S. 472.

Bartlett were issued, every federal court to consider the issue has held that this federal law bars retailers (and other entities in the supply chain of generic drugs that do not hold FDA-approved applications) from changing warning labeling and, therefore, that state-law warnings claims are preempted against those parties. Notably, a federal judge recently performed this analysis for the same drug products at issue in this case, ranitidine medications, in a multidistrict litigation ("MDL") pending in Florida federal court. The MDL judge dismissed with prejudice all counts against retailers and other entities that do not hold FDA-approved applications of ranitidine-containing products as preempted.

Moreover, arguments that retailers can warn outside of the label printed on the drug's container—such as by shelf tag at a retail location—are unpersuasive. The pertinent federal law defines "labeling" broadly, to include not just the printed label appearing on the drug's container or wrapping, but also advertisements or other communications accompanying the sale of a drug. Thus, as numerous courts have held, when (as here) federal law bars a party from changing the FDA-approved drug "labeling," that same federal law *also* prohibits communicating warnings that do not appear on the printed drug label though any other medium.

Here, Target Corporation and 7-Eleven, Inc. ("Retailer Defendants") do not hold the applications for the ranitidine medications they sold in the state of California. Request for Judicial Notice ("RJN") ¶ 2, Ex. A. Thus, under the principles of *Mensing* and *Bartlett* as persuasively applied to claims against retailers by the MDL judge and by other federal courts, federal law governs warnings for FDA-approved drug products in a manner that preempts Retailer Defendants from providing a Proposition 65 warning with ranitidine medications. As such, Plaintiff Center for Environmental Health's ("CEH" or "Plaintiff") Proposition 65 claim falls squarely within the statutory exception in Section 25249.10(a). Retailer Defendants' demurrer should be sustained.

II. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

Retailer Defendants adopt and incorporate by reference as if fully stated herein the Relevant Factual and Procedural Background section of Generic Manufacturers' Joint

Memorandum of Points and Authorities In Support of Demurrer of Plaintiff's Second Amended Complaint ("Generics' Brief"). Additional facts pertinent to Retailer Defendants are included in the Argument section, *infra*.

III. DEMURRER STANDARD

Retailer Defendants adopt and incorporate by reference as if fully stated herein the Demurrer Standard section of Generics' Brief.

IV. ARGUMENT

A. Proposition 65 recognizes—and yields to—federal preemption

Retailer Defendants adopt and incorporate by reference as if fully stated herein the Argument Section Part A of Generics' Brief, which apply equally to Retailer Defendants. As set forth in Generics' Brief, California's Proposition 65—the Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5-25249.14—is a right-to-know warning statute that prohibits businesses from "knowingly and intentionally" exposing California consumers to chemicals known to the State to cause cancer without a warning. Cal. Health & Safety Code § 25249.6. Specifically, the statute requires that businesses give a "clear and reasonable warning" that "clearly communicate[s]" that the "chemical ... is known ... to cause cancer" before exposure occurs. *Id.*, §§ 25249.6; 25249.10(b); 25601.

But Proposition 65 provides that the requirements stated in Section 25249.6 "shall not apply to . . . [a]n exposure for which federal law governs warning in a manner that preempts state authority." Cal. Health & Safety Code § 25249.10(a). And, under the controlling authority of *Mensing*, and as persuasively applied to retailers and others that do not hold FDA-approved applications by the preemption ruling in the *Zantac MDL* and other authorities stated below (*see* Arg. B, *infra* at 3-8), "federal law governs warning in a manner that preempts state authority." Cal. Health & Safety Code § 25249.10(a). And, because the Section 25249.10(a) exception applies, it is irrelevant that Plaintiff has alleged that Retailer Defendants "can reduce or eliminate NDMA from the Products by using cleaner ingredients and manufacturing processes and more careful storage techniques." SAC ¶ 24. In other words, since federal law makes it impossible for

Retailer Defendants to change the ranitidine medications' FDA-approved *warnings* and thereby preempts state authority regarding *warnings*, the Section 25249.10(a) exception applies and bars Plaintiff's Proposition 65 claim. And because the allegations in SAC ¶ 24 all involve actions *other than* warnings those allegations are simply irrelevant to the analysis.

Therefore, and for the additional reasons given below, this Court should sustain Retailer Defendants' demurrer and dismiss the Second Amended Complaint with prejudice.

B. Impossibility preemption bars Plaintiff's Proposition 65 claim against Retailer Defendants

Retailer Defendants adopt and incorporate by reference as if fully stated herein the Argument Section Part B of Generics' Brief. In addition, Retailer Defendants state as follows:

1. *Mensing* and *Bartlett* mandate the preemption of failure-to-warn claims against retailers that use federally required drug labeling

The foundation of any preemption analysis is the Supremacy Clause, which establishes that federal law "shall be the supreme Law of the Land. . . ." U.S. Const., Art. VI, cl. 2. Thus, when state and federal law directly conflict, making it impossible for a private party to comply with both, "state law must give way." *Mensing* 564 U.S. at 617. In *Mensing,* the Supreme Court explained that the sole "question for 'impossibility' [preemption] is whether the private party could *independently* do under federal law what state law requires of it[.]" *Id.* at 620 (emphasis added). If it cannot lawfully do so, the claims are preempted and must be dismissed. *Id.*; *see also In re Zantac (Ranitidine) Prods. Liab. Litig.,* No. 2924 20-MD-2924; 2020 WL 7864213 (S.D. Fla. Dec. 31, 2020) at *13 (dismissing claims against generic-drug manufacturers of ranitidine based on impossibility preemption); *In re Zantac (Ranitidine) Prods. Liab. Litig.;* No. 2924 20-MD-2924; 2020 WL 7864585 (S.D. Fla. Dec. 31, 2020) at *13-14 (dismissing claims against retailers of ranitidine based on impossibility preemption).

As set forth in greater detail in Generics' Brief, the United States Supreme Court in *Mensing* applied that principle to hold that state-law failure-to-warn claims against generic manufacturers are federally preempted; federal law imposes a duty of "sameness" for generic

manufacturers to use the same warning labeling as the equivalent brand name drug that directly conflicts with any purported state-law duty to provide new or different warnings, such that it is impossible to satisfy both. Generics' Br. at 6-9; *see also* 564 U.S. at 623-24.

Two years later, the Supreme Court held in *Bartlett* that federal law *also* preempts state-law *design*-defect claims against generic drug manufacturers. Generics' Br. at 9-10; *Bartlett*, 570 U.S. 475-76. The *Bartlett* Court explained that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based," and once the FDA approves a generic drug's design, changes to the "qualitative or quantitative formulation of the drug product" cannot be made absent FDA approval. *Id.*; *Bartlett*, 570 U.S. at 483-84. The *Bartlett* Court also squarely rejected what it referred to as a "stop-selling" argument: that a manufacturer could satisfy both its state- and federal-law duties by choosing not to make the FDA-approved medicine at all. *Id.*; *Bartlett*, 570 U.S. at 488-90.

The same preemption principles that *Mensing* and *Bartlett* applied to failure-to-warn and design-defect claims against generic manufacturers are equally applicable to similar claims brought against packagers and retailers of generic drug products. Simply put, just as for generic drugs, there is a clear and direct conflict between what federal law permits Retailer Defendants to do with respect to the drugs they package and sell, and Plaintiff's state-law claim under Proposition 65, such that the state-law Proposition 65 claim "must give way." *See Mensing*, 564 U.S. at 617.

Federal law (specifically, the Food, Drug, & Cosmetic Act ("FDCA")) provides that any new drug intended for human use to be legally marketed and sold in the United States must be pre-approved by the FDA under a New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355 ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."); 21 U.S.C. § 331(d) (prohibiting "the introduction or delivery for introduction into interstate commerce of any article

in violation of section . . . 355 . . . of this title."). Only the company that holds the FDA-approved NDA drug application may unilaterally make certain changes to medication labeling, and only an NDA or ANDA holder may apply to FDA for permission to make other changes to its labeling or design. *See* 21 C.F.R. § 314.70(b) (setting forth the procedures for a drug "applicant" to supplement an existing drug application and seek FDA approval prior to making certain changes to a drug's labeling and design); 21 C.F.R. § 314.70(c)(6) ("holder of the approved NDA" may, in certain specified circumstances, unilaterally change an FDA-approved drug products' warning labeling and "commence distribution of the drug product involved upon receipt by the agency of a supplement for the change.").[2]

Thus, for generic drugs, neither the ANDA-holder (*e.g.*, the generic manufacturer) nor any other party (such as a retailer) can make unilateral changes to warning labeling or drug design because of the duty of "sameness" to have the same labeling and design as the brand-name product. *See Mensing*, 564 U.S. at 623-24. And a party that does not hold an ANDA for a generic drug (such as, here, Retailer Defendants) cannot even submit a formal drug application supplement to FDA requesting that FDA approve a labeling or design change.

Importantly, the FDCA defines "labeling" to include not only the printed label that appears on a drug product or its container, but also "all labels and other written, printed, or graphic matter . . . accompanying such article." *Strayhorn v. Wyeth Pharms., Inc.* (6th Cir. 2014) 737 F.3d 378, 394 (quoting 21 U.S.C. § 321(m)). And the United States Supreme Court has held that "[o]ne article or thing is accompanied by another when it supplements or explains it. . . . No physical attachment one to the other is necessary." *Id.* (quoting *Kordel v. United States* (1948)

---

[2] A generic drug manufacturer generally must comply with the provisions of 21 C.F.R. § 314.70, including its provisions regarding submission of supplements to FDA. *See* 21 C.F.R. § 314.97. But in *Mensing* the Supreme Court explained that because "a manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name's [label]" a generic manufacturer cannot use the process under § 314.70(c)(6) to *unilaterally* change a generic drug's labeling. 564 U.S. at 613-15, 624-25. Because federal impossibility preemption considers only actions that a party can *unilaterally* take, and the duty of "sameness" bars generic-drug manufacturers from unilaterally changing their labels, failure to warn claims are preempted. *Id.* at 619-20

335 U.S. 345, 349-50). Thus, advertising, promotion materials, or other forms of communicating warnings fall within the federal definition of "labeling." *Id.* Consequently, companies that do not hold an NDA for a drug cannot communicate warnings to consumers through advertising or other means that differ from the FDA-approved NDA labeling.

2. *Mensing* and *Bartlett* preempt Plaintiff CEH's Proposition 65 warning claim.

CEH alleges that Retailer Defendants "manufacture, distribute, and/or sell" over-the-counter ("OTC") acid-reducing medications containing ranitidine ("OTC ranitidine medications"). SAC ¶¶ 6, 10. CEH asserts that Proposition 65 required Retailer Defendants to directly warn consumers that using the OTC ranitidine medications allegedly exposes them to the chemical n-nitrosodimethylamine ("NDMA"), an alleged carcinogen. On that basis, CEH seeks injunctive relief, civil penalties, and attorneys' fees.

Plaintiff agrees Retailer Defendants do not hold the FDA-approved applications (*e.g.*, an NDA or ANDA) for the OTC ranitidine medications they sold in California. And this Court may take judicial notice that Retailer Defendants do not hold FDA-approved applications for OTC ranitidine medications, because that fact is "not reasonably subject to dispute" and is "capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy." Cal. Code Evid. § 452(h). The FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (41st Ed. 2021), commonly known as the "Orange Book" is an authoritative publication which identifies all drug products FDA has approved on the basis of safety and effectiveness by the product's active pharmaceutical ingredient. RJN ¶ 2, Ex. A. The Orange Book listings for a drug product include the name of the company holding the FDA-approved drug application (NDA or ANDA) for every ranitidine product that FDA has ever approved. *Id.* ¶ 2.

Here, Target Corporation and 7-Eleven, Inc. are **not** listed in the Orange Book as the holders of an FDA-approved application for **any** form of ranitidine product. *Id.* ¶ 2. And because

Retailer Defendants did not hold the FDA-approved applications for OTC ranitidine medications, they lacked the ability under federal law to alter the labeling or design of those medications.

Thus, under *Mensing*, CEH's Proposition 65 warning allegations are preempted as to the Retailer Defendants. And, because federal law defines "labeling" broadly to include all labels and other written matter accompanying the product, the preemption applies to claims that Retailer Defendants could have issued warnings by adding new warnings to the printed labels on the ranitidine medications and to allegations that warnings could have been communicated by some other medium, for example by retail shelf tags or by electronic means at checkout. *See Strayhorn, supra*, 737 F.3d at 394. Finally, to the extent that CEH alleges that Retailer Defendants could have changed the ranitidine medications' design (*see, e.g.*, SAC ¶ 24 (alleging that defendants could have altered the "ingredients" used in making ranitidine)), such claims are preempted under *Bartlett*.

3. The *Zantac MDL* court and numerous other courts have dismissed failure-to-warn claims against retailers and other non-applicants as preempted under *Mensing* and *Bartlett*.

As discussed in the Generics' Brief, starting in September 2019, ranitidine-containing products began to be withdrawn from the market shortly after a Citizen Petition asked the FDA to recall the products due to purportedly high NDMA levels. Generics' Br. at 2. In April 2020, the FDA expanded on earlier guidance by formally recommending the withdrawal of *all* ranitidine products from the market. *Id.* The well-publicized nationwide withdrawal prompted hundreds of ranitidine lawsuits, most of which have been consolidated in a federal multidistrict litigation ("MDL") presided over by Judge Robin Rosenberg in the U.S. District Court for the Southern District of Florida. *Id.* Generics' Brief summarizes Judge Rosenberg's recent order granting the dismissal on federal preemption grounds of all state-law claims in the three MDL Master Complaints against the generic-drug manufacturer defendants, including the dismissal with prejudice of all claims premised on a failure to warn consumers about the presence of NDMA. *Id.* at 2-4; *In re Zantac (Ranitidine) Prods. Liab. Litig.*; 2020 WL 7864213 No. 2924 20-

MD-2924 at *14, 25 (S.D. Fla. Dec. 31, 2020).

On the same day as Judge Rosenberg issued her order dismissing as preempted all claims against the generic-drug manufacturer defendants in the MDL, she also issued a companion order dismissing all claims brought against the MDL retailer defendants across all three Master Complaints as federally preempted. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*; 2020 WL 7864585 No. 2924 20-MD-2924 at *23 (S.D. Fla. Dec. 31, 2020). The MDL court explained that *Mensing* and *Bartlett*, the United States Supreme Court's landmark generic-drug preemption rulings, require the dismissal of state-law failure-to-warn or design claims "where the defendant had no ability to alter a label or alter a design" of a drug (*e.g.*, when the defendant never held the FDA-approved application for the drug's sale or divested it to another company). *Id.* at *12. Because the MDL retailer defendants lacked any ability under federal law to unilaterally alter ranitidine medications' labeling or design, the MDL court held that federal law preempts, and requires dismissal **with prejudice**, of "all of the Plaintiffs' state-law claims against the [retailer] Defendants . . . premised upon the contention that ranitidine's design or label were deficient." *Id.* at *14.

Judge Rosenberg noted that her order was supported by numerous cases in which state-law claims against retailers or other companies that did **not** hold NDAs or ANDAs were dismissed as federally preempted. *Id* at *44-45.; *see also, e.g., Greager v. McNeil-PPC, Inc.* (N.D. Ill. 2019) 414 F. Supp. 3d 1137, 1142 (noting the "key distinction in the relevant regulatory structure and case law is not between prescription and non-prescription drugs but between NDA holders and ANDA holders" and dismissing all claims relating to an OTC drug against both the generic manufacturer and the retailer, including claims for failure to warn); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.* (6th Cir. 2014) 756 F.3d 917, 940 (holding that when a brand-name manufacturer divested itself of the NDA application for a drug, claims against it must be preempted because "[a]fter the divestiture, [brand-name manufacturer] had no more power to change the label than did [a generic drug manufacturer]."); *Smith v. Teva Pharm. USA, Inc.* (S.D. Fla. 2020) 437 F. Supp. 3d 1159, 1165-66 (holding that preemption

applies to warning claims against a defendant that distributed a brand-name drug product because the defendant "could not have unilaterally changed [the drug's] labels. . . . The Court finds no reason to depart from the wealth of authority clearly stating that a company that does not hold an NDA . . . is powerless to submit label changes to the FDA."); *Brazil v. Janssen Research & Dev. LLC* (N.D. Ga. 2016) 196 F. Supp. 3d 1351, 1364–65 (granting motion to dismiss as to distributor defendant on preemption grounds because distributor defendant "is not the NDA applicant and thus cannot seek to change [the drug's] label."). In contrast, the MDL plaintiffs "provided no citation to a case where similar claims against retailers (or distributors) survived a pre-emption analysis." *In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 2924 20-MD-2924; 2020 WL 7864585 at 8-9* (S.D. Fla. Dec. 31, 2020).

Simply put, every reported decision to consider the issue has held that the principles of impossibility preemption and analysis of controlling federal law and regulations governing drug products set forth in *Mensing* and *Bartlett* require the preemption of claims against non-applicants, including retailers. This Court should hold similarly and dismiss Plaintiff's Proposition 65 failure-to-warn claim as federally preempted.

C. Retailer Defendants are not asking the court to find express preemption under 21 U.S.C. § 379r, and that section is irrelevant to and does not defeat implied preemption under *Mensing* and *Bartlett*

Retailer Defendants adopt and incorporate by reference as if fully stated herein the Argument Section Part C of Generics' Brief, which apply equally to Retailer Defendants. In addition, Retailer Defendants note that Judge Rosenberg's preemption ruling in the *Zantac MDL* specific to the MDL retailer defendants also rejected the notion that couching failure-to-warn claims against ranitidine as parallel "misbranding" claims was, as a matter of law, insufficient to defeat federal implied preemption. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*,; No. 2924 20-MD-29242020 WL 7864585 at *13-14 (S.D. Fla. Dec. 31, 2020).

///

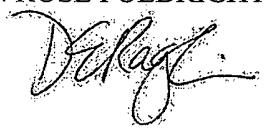
///

V. CONCLUSION

Based upon the foregoing, Retailer Defendants respectfully requests that their Demurrer to CEH's SAC be sustained, in its entirety, without leave to amend.

DATED: February 19, 2021

NORTON ROSE FULBRIGHT US LLP



"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____

Jeffery Margulies
Lauren A. Shoor
Attorneys for Defendant
TARGET CORPORATION

DATED: February 19, 2021

GREENBERG TRAURIG, LLP

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____

Will Wagner
Attorneys for Defendant
7-ELEVEN, INC.

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing ☐ the original / ☐ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents. Note: Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
☐ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
☐ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fac: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 15

Deepi Miller (SBN 272497)
millerde@gtlaw.com
Willis M. Wagner (SBN 310900)
wagnerw@gtlaw.com
GREENBERG TRAURIG, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814-3938
Telephone: (916) 442-1111
Facsimile: (916) 448-1709

Trenton H. Norris (SBN 164781)
trent.norris@arnoldporter
Vanessa C. Adriance (SBN 24746)
vanessa.adriance@arnoldporter.com
ARNOLD & PORTER
Three Embarcadero Center, 10th Floor
San Francisco, CA 94111-4075
Telephone: (415) 471-3303
Facsimile: (415) 471-3400

Attorneys for Defendant
7-ELEVEN, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, et. al.,

Defendants.

CASE NO. RG20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

DECLARATION OF WILLIS M. WAGNER IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[*Filed concurrently with Demurrer, Memorandum of Points and Authorities; Request for Judicial Notice; Declaration of Lauren A. Shoor and Proposed Order*]

RESERVATION NO.: R-2240281

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**

Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

I, Willis M. Wagner, declare as follows:

1. I am an attorney duly admitted to practice before this Court and all courts in the State of California with the law firm of Greenberg Traurig, LLP, attorneys of record for Defendant 7-Eleven, Inc. I submit this declaration in accordance with California Code of Civil Procedure Section 430.41(a). I have personal knowledge of the following and can and do competently testify thereto.

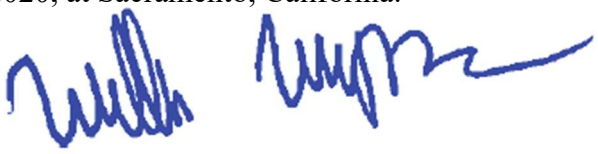
2. On February 12, 2021, I participated in a telephone conference with counsel for Defendant Target Corporation ("Target") and Plaintiff Center for Environmental Health ("CEH") to meet and confer on Target and 7-Eleven's (collectively "Defendants") contemplated joint demurrer to CEH's Second Amended Complaint which asserts a single cause of action against Defendants for alleged violation of Health & Safety Code § 25249.6, Proposition 65.

3. We discussed the legal support for Defendants' contemplated demurrer on the grounds that CEH's claim is preempted by federal law.

4. On February 12, 2021, following our telephone conference, counsel for Target and I emailed counsel for CEH the citations to the legal authorities discussed during our telephone conference.

5. Counsel for CEH stated on the call that he would follow up by email if he believed the objections raised in the demurrer could be resolved, and CEH's counsel did not respond to our emails to indicate that the objections raised in the demurrer could be resolved.

I declare under penalty of perjury of the laws of the State of California that the foregoing is true and correct. Executed this 19th day of February, 2020, at Sacramento, California.



Willis M. Wagner

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **DECLARATION OF WILLIS M. WAGNER IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents. **Note:** Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fac: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 16

Jeffrey B. Margulies (SBN 126002)
jeff.margulies@nortonrosefulbright.com
Lauren A. Shoor (SBN 280788)
lauren.shoor@nortonrosefulbright.com
NORTON ROSE FULBRIGHT US LLP
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Attorneys for Defendant
TARGET CORPORATION

Trenton H. Norris (SBN 164781)
trent.norris@arnoldporter
Vanessa C. Adriance (SBN 24746)
vanessa.adriance@arnoldporter.com
ARNOLD & PORTER
Three Embarcadero Center, 10th Floor
San Francisco, CA 94111-4075
Telephone: (415) 471-3303
Facsimile: (415) 471-3400

Attorneys for Defendant
7-ELEVEN, INC.

Will Wagner (SBN 310900)
wagnerw@gtlaw.com
GREENBERG TRAUIG, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814
Telephone: 916-442-1111
Facsimile: 916-448-1709

Attorneys for Defendant
7-ELEVEN, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG20054985

Assigned for All Purposes to Honorable Winifred Y. Smith - Dept. 21

JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[Filed concurrently with Notice of Demurrer; Joint Memorandum of Points and Authorities; Declaration of Lauren A. Shoor and Proposed Order]

RESERVATION NO.: R-2242040

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

Pursuant to California Evidence Code §§ 452 and 453, and on such other grounds as the Court may consider, Defendants Target Corporation and 7-Eleven, Inc. (hereinafter "Defendants") bring this joint Request for Judicial Notice respectfully submitting that the exhibit accompanying this Request supports Defendants' joint demurrer to the Second Amended Complaint brought by Plaintiff Center for Environmental Health.

Defendants hereby request the Court take judicial notice of the document described below pursuant to Evid. Code § 452(c). Alternatively, Defendants make this Request pursuant to Evid. Code § 452(h) and/or § 453.

1. A copy of search results from FDA's website entitled "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" (hereinafter "Orange Book") listing the companies authorized to manufacture and sell ranitidine by way of an approved New Drug, or Abbreviated New Drug, Application. A true and correct copy of the downloaded document is attached hereto as **Exhibit A.**

Pursuant to Evid. Code § 452(c), the Court may take judicial notice of "[o]fficial acts of the legislative, executive, and judicial departments of the United States and of any state of the United States." "Official acts include records, reports and orders of administrative agencies." *Rodas v. Speigel*, (2001) 87 Cal. App. 4th 513, 518. An authorization by FDA is a formal act by a department of the executive branch. Thus, pursuant to Evid. Code § 452(c), the Court may take judicial notice of Exhibit A.

Defendants alternatively request the Court take judicial notice of Exhibit A pursuant to either Evid. Code § 452(h) or § 453. First, Evid. Code § 452(h) provides that the Court may take judicial notice of "[f]acts and propositions that are not reasonably subject to dispute and are capable of immediate and accurate determination by resort to courses of reasonable accuracy." Courts may take judicial notice of matters of public records outside the pleadings whose accuracy cannot reasonably be questioned. *See MGIC Indemn. Corp. v. Weisman* (9th Cir. 1986) 803 F.2d 500, 504; *Seely v. Cumberland Packing Corp.*; No. 10–CV–02019–LHK; 2010 WL 5300923, at *7 n.5. The FDA's Orange Book is not reasonably subject to dispute and is capable of immediate and accurate

determination by a source of reasonably indisputable accuracy. The Orange Book confirms that Defendants did not submit and do not hold New Drug, or Abbreviated New Drug, Applications to FDA for ranitidine. Plaintiff does not dispute this fact, and Plaintiff will not oppose the Court granting the Request. Second, Evid. Code §453 provides that a request for judicial notice shall be granted if the requesting party "[g]ives each adverse party sufficient notice of the request…" and "Furnishes the Court with sufficient information to enable it to take judicial notice of the matter." Defendants have submitted the information herein to both Plaintiff and the Court confirming that Defendants do not hold New Drug, or Abbreviated New Drug, Applications for ranitidine.

DATED: February 19, 2021

NORTON ROSE FULBRIGHT US LLP

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____

Jeffery Margulies
Lauren A. Shoor
Attorneys for Defendant
TARGET CORPORATION

DATED: February 19, 2021

GREENBERG TRAURIG, LLP

"SIGNED ON BEHALF OF WITH PERSMISSION"

By: _____

Will Wagner
Attorneys for Defendant
7-ELEVEN, INC.

EXHIBIT A

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A211058	CAPSULE	ORAL	EQ 150MG BASE	AB			AUROBINDO PHARMA LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075742	CAPSULE	ORAL	EQ 150MG BASE	AB			DR REDDYS LABORATORIES LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074655	CAPSULE	ORAL	EQ 150MG BASE	AB			SANDOZ INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A211058	CAPSULE	ORAL	EQ 300MG BASE	AB			AUROBINDO PHARMA LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075742	CAPSULE	ORAL	EQ 300MG BASE	AB			DR REDDYS LABORATORIES LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074655	CAPSULE	ORAL	EQ 300MG BASE	AB		RS	SANDOZ INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A079076	INJECTABLE	INJECTION	EQ 25MG BASE/ML	AP			MYLAN LABORATORIES LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074777	INJECTABLE	INJECTION	EQ 25MG BASE/ML	AP			WEST-WARD PHARMACEUTICALS INTERNATIONAL LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077458	INJECTABLE	INJECTION	EQ 25MG BASE/ML	AP			WEST-WARD PHARMACEUTICALS INTERNATIONAL LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A091534	INJECTABLE	INJECTION	EQ 25MG BASE/ML	AP			ZYDUS PHARMACEUTICALS USA INC
RX	RANITIDINE HYDROCHLORIDE	ZANTAC	N019090	INJECTABLE	INJECTION	EQ 25MG BASE/ML	AP	RLD	RS	TELIGENT OU
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A090623	SYRUP	ORAL	EQ 15MG BASE/ML	AA			AUROBINDO PHARMA LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078890	SYRUP	ORAL	EQ 15MG BASE/ML	AA			LANNETT CO INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A091288	SYRUP	ORAL	EQ 15MG BASE/ML	AA			LANNETT CO INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077405	SYRUP	ORAL	EQ 15MG BASE/ML	AA		RS	PHARMACEUTICAL ASSOCIATES INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074680	TABLET	ORAL	EQ 150MG BASE	AB			APOTEX INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A076705	TABLET	ORAL	EQ 150MG BASE	AB			DR REDDYS LABORATORIES INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078542	TABLET	ORAL	EQ 150MG BASE	AB			GLENMARK PHARMACEUTICALS INC USA
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075180	TABLET	ORAL	EQ 150MG BASE	AB			PAR PHARMACEUTICAL INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074467	TABLET	ORAL	EQ 150MG BASE	AB			SANDOZ INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A211289	TABLET	ORAL	EQ 150MG BASE	AB			VKT PHARMA PRIVATE LTD
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074680	TABLET	ORAL	EQ 300MG BASE	AB			APOTEX INC

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A076705	TABLET	ORAL	EQ 300MG BASE	AB			DR REDDYS LABORATORIES INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078542	TABLET	ORAL	EQ 300MG BASE	AB			GLENMARK PHARMACEUTICALS INC USA
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075180	TABLET	ORAL	EQ 300MG BASE	AB			PAR PHARMACEUTICAL INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074467	TABLET	ORAL	EQ 300MG BASE	AB			SANDOZ INC
RX	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A211289	TABLET	ORAL	EQ 300MG BASE	AB			VKT PHARMA PRIVATE LTD
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A207579	TABLET	ORAL	EQ 75MG BASE				AUROBINDO PHARMA LTD
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075294	TABLET	ORAL	EQ 75MG BASE				DR REDDYS LABORATORIES LTD
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A076195	TABLET	ORAL	EQ 75MG BASE				L PERRIGO CO
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210250	TABLET	ORAL	EQ 75MG BASE				UNIQUE PHARMACEUTICAL LABORATORIES A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A207578	TABLET	ORAL	EQ 150MG BASE				AUROBINDO PHARMA LTD
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078192	TABLET	ORAL	EQ 150MG BASE				DR REDDYS LABORATORIES LTD
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A091429	TABLET	ORAL	EQ 150MG BASE				PERRIGO R AND D CO
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A091429	TABLET	ORAL	EQ 150MG BASE				PERRIGO R AND D CO
OTC	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210228	TABLET	ORAL	EQ 150MG BASE				UNIQUE PHARMACEUTICAL LABORATORIES A DIVISION OF J.B. CHEMICALS AND PHARMACEUTICALS LTD
OTC	RANITIDINE HYDROCHLORIDE	ZANTAC 150	N021698	TABLET	ORAL	EQ 150MG BASE		RLD	RS	SANOFI US
OTC	RANITIDINE HYDROCHLORIDE	ZANTAC 150	N021698	TABLET	ORAL	EQ 150MG BASE		RLD		SANOFI US
OTC	RANITIDINE HYDROCHLORIDE	ZANTAC 75	N020520	TABLET	ORAL	EQ 75MG BASE		RLD		SANOFI US
DISCN	RANITIDINE BISMUTH CITRATE	TRITEC	N020559	TABLET	ORAL	400MG				GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A209859	CAPSULE	ORAL	EQ 150MG BASE				AJANTA PHARMA LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A211893	CAPSULE	ORAL	EQ 150MG BASE				APPCO PHARMA LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075564	CAPSULE	ORAL	EQ 150MG BASE				MYLAN PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210681	CAPSULE	ORAL	EQ 150MG BASE				NOVITIUM PHARMA LLC

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075557	CAPSULE	ORAL	EQ 150MG BASE				TEVA PHARMACEUTICALS USA INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A209859	CAPSULE	ORAL	EQ 300MG BASE				AJANTA PHARMA LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A211893	CAPSULE	ORAL	EQ 300MG BASE				APPCO PHARMA LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075564	CAPSULE	ORAL	EQ 300MG BASE				MYLAN PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210681	CAPSULE	ORAL	EQ 300MG BASE				NOVITIUM PHARMA LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075557	CAPSULE	ORAL	EQ 300MG BASE				TEVA PHARMACEUTICALS USA INC
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 150	N020095	CAPSULE	ORAL	EQ 150MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**		RLD		GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 300	N020095	CAPSULE	ORAL	EQ 300MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**		RLD		GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 150	N020251	GRANULE, EFFERVESCENT	ORAL	EQ 150MG BASE/PACKET				GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074764	INJECTABLE	INJECTION	EQ 25MG BASE/ML				BEDFORD LABORATORIES DIV BEN VENUE LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC IN PLASTIC CONTAINER	N019593	INJECTABLE	INJECTION	EQ 1MG BASE/ML				TELIGENT OU
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC IN PLASTIC CONTAINER	N019593	INJECTABLE	INJECTION	EQ 50MG BASE/100ML				TELIGENT OU
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A076124	SYRUP	ORAL	EQ 15MG BASE/ML				ACTAVIS MID ATLANTIC LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A091078	SYRUP	ORAL	EQ 15MG BASE/ML				AKORN OPERATING CO LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078312	SYRUP	ORAL	EQ 15MG BASE/ML				AMNEAL PHARMACEUTICALS
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A090054	SYRUP	ORAL	EQ 15MG BASE/ML				ANDA REPOSITORY LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077602	SYRUP	ORAL	EQ 15MG BASE/ML				APOTEX INC

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078684	SYRUP	ORAL	EQ 15MG BASE/ML				NOSTRUM LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A091091	SYRUP	ORAL	EQ 15MG BASE/ML				NOSTRUM LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078448	SYRUP	ORAL	EQ 15MG BASE/ML				RANBAXY INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077476	SYRUP	ORAL	EQ 15MG BASE/ML				TARO PHARMACEUTICALS USA INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A090102	SYRUP	ORAL	EQ 15MG BASE/ML				TORRENT PHARMA INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A079211	SYRUP	ORAL	EQ 15MG BASE/ML				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A079212	SYRUP	ORAL	EQ 15MG BASE/ML				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC	N019675	SYRUP	ORAL	EQ 15MG BASE/ML		RLD		GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075212	TABLET	ORAL	EQ 75MG BASE				ANI PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075296	TABLET	ORAL	EQ 75MG BASE				ANI PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075167	TABLET	ORAL	EQ 75MG BASE				APOTEX INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075094	TABLET	ORAL	EQ 75MG BASE				CONTRACT PHARMACAL CORP
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075497	TABLET	ORAL	EQ 75MG BASE				MYLAN PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075254	TABLET	ORAL	EQ 75MG BASE				RANBAXY PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075519	TABLET	ORAL	EQ 75MG BASE				SANDOZ INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A201745	TABLET	ORAL	EQ 75MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A209160	TABLET	ORAL	EQ 75MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075132	TABLET	ORAL	EQ 75MG BASE				SUN PHARMACEUTICAL INDUSTRIES LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A076760	TABLET	ORAL	EQ 75MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078884	TABLET	ORAL	EQ 75MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077824	TABLET	ORAL	EQ 150MG BASE				AMNEAL PHARMACEUTICALS NY LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074488	TABLET	ORAL	EQ 150MG BASE				ANI PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077426	TABLET	ORAL	EQ 150MG BASE				ANI PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A200172	TABLET	ORAL	EQ 150MG BASE				APOTEX INC

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074662	TABLET	ORAL	EQ 150MG BASE				BOEHRINGER INGELHEIM CORP
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210243	TABLET	ORAL	EQ 150MG BASE				GRANULES INDIA LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210243	TABLET	ORAL	EQ 150MG BASE				GRANULES INDIA LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075165	TABLET	ORAL	EQ 150MG BASE				HERITAGE PHARMA LABS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074023	TABLET	ORAL	EQ 150MG BASE				MYLAN PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074552	TABLET	ORAL	EQ 150MG BASE				MYLAN PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A203694	TABLET	ORAL	EQ 150MG BASE				NOSTRUM LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075000	TABLET	ORAL	EQ 150MG BASE				RANBAXY PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A200536	TABLET	ORAL	EQ 150MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A205512	TABLET	ORAL	EQ 150MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A209161	TABLET	ORAL	EQ 150MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210010	TABLET	ORAL	EQ 150MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075439	TABLET	ORAL	EQ 150MG BASE				SUN PHARMACEUTICAL INDUSTRIES LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074864	TABLET	ORAL	EQ 150MG BASE				WATSON LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075208	TABLET	ORAL	EQ 150MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078653	TABLET	ORAL	EQ 150MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078701	TABLET	ORAL	EQ 150MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077824	TABLET	ORAL	EQ 300MG BASE				AMNEAL PHARMACEUTICALS NY LLC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074488	TABLET	ORAL	EQ 300MG BASE				ANI PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A077426	TABLET	ORAL	EQ 300MG BASE				ANI PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074662	TABLET	ORAL	EQ 300MG BASE				BOEHRINGER INGELHEIM CORP
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075165	TABLET	ORAL	EQ 300MG BASE				HERITAGE PHARMA LABS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074023	TABLET	ORAL	EQ 300MG BASE				MYLAN PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074552	TABLET	ORAL	EQ 300MG BASE				MYLAN PHARMACEUTICALS INC

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A203694	TABLET	ORAL	EQ 300MG BASE				NOSTRUM LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075000	TABLET	ORAL	EQ 300MG BASE				RANBAXY PHARMACEUTICALS INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A205512	TABLET	ORAL	EQ 300MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A210010	TABLET	ORAL	EQ 300MG BASE				STRIDES PHARMA GLOBAL PTE LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075439	TABLET	ORAL	EQ 300MG BASE				SUN PHARMACEUTICAL INDUSTRIES LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A074864	TABLET	ORAL	EQ 300MG BASE				WATSON LABORATORIES INC
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A075208	TABLET	ORAL	EQ 300MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	RANITIDINE HYDROCHLORIDE	A078701	TABLET	ORAL	EQ 300MG BASE				WOCKHARDT LTD
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 150	N018703	TABLET	ORAL	EQ 150MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**		RLD		GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 300	N018703	TABLET	ORAL	EQ 300MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**		RLD		GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 150	N020251	TABLET, EFFERVESCENT	ORAL	EQ 150MG BASE				GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 25	N020251	TABLET, EFFERVESCENT	ORAL	EQ 25MG BASE				GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE
DISCN	RANITIDINE HYDROCHLORIDE	ZANTAC 75	N020745	TABLET, EFFERVESCENT	ORAL	EQ 75MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**		RLD		SANOFI US

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents. **Note:** Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. george.gigounas@dlapiper.com Greg Sperla, Esq. greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fac: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 17

Jeffrey B. Margulies (SBN 126002)
jeff.margulies@nortonrosefulbright.com
Lauren A. Shoor (SBN 280788)
lauren.shoor@nortonrosefulbright.com
NORTON ROSE FULBRIGHT US LLP
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Attorneys for Defendant
TARGET CORPORATION

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

[*Filed concurrently with Notice of Demurrer; Joint Memorandum of Points and Authorities; Joint Request for Judicial Notice and Proposed Order*]

RESERVATION NO.: R-2242040

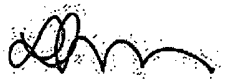
Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

I, Lauren Shoor, declare:

1. I am a lawyer duly admitted to practice before this court and all courts in the State of California and am a senior associate with the law firm Norton Rose Fulbright US LLP, attorneys for Defendant Target Corporation. I make this declaration in support of the Request for Judicial Notice brought by Defendants Target Corporation and 7-Eleven, Inc. in support of their Joint Demurrer to Plaintiff's Second Amended Complaint. I have personal knowledge of the facts contained herein and if called could testify truthfully to them.

2. On February 16, 2021, I accessed from the FDA's website a webpage entitled, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations." The address of the webpage is https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. On this webpage, under the heading "Find Approved Drugs," I entered the term "ranitidine" into the search field "Search by Proprietary Name, Active Ingredient or Application number." The search resulted in a listing of one hundred twenty two (122) applicant holders represented to hold applications for ranitidine products. I printed out a copy of the search result from this webpage. A true and correct copy of the search result is attached as Exhibit A to the Request for Judicial Notice.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 18th day of February, 2021 at Los Angeles, California.



Lauren Shoor

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **DECLARATION OF LAUREN A. SHOOR IN SUPPORT OF JOINT REQUEST FOR JUDICIAL NOTICE. IN SUPPORT OF DEFENDANTS TARGET CORPORATION AND 7-ELEVEN, INC.'S DEMURRER TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing ☐ the original / ☐ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents.
Note: Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
☐ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
☐ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fac: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.

Exhibit 18

Jeffrey B. Margulies (SBN 126002)
jeff.margulies@nortonrosefulbright.com
Lauren A. Shoor (SBN 280788)
lauren.shoor@nortonrosefulbright.com
NORTON ROSE FULBRIGHT US LLP
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494

Attorneys for Defendant
TARGET CORPORATION

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH, a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY; TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.; GRANULES USA, INC.; 7-ELEVEN,INC.; SANOFI-AVENTIS U.S. LLC; CHATTEM INC.; DR. REDDY'S LABORATORIES LOUISIANA, LLC; DR. REDDY'S LABORATORIES, INC. and DOES 1 to 20, inclusive, *et. al.*,

Defendants.

Case No. RG20054985

Assigned for All Purposes to
Hon. Winifred Y. Smith - Dept 21

[PROPOSED] ORDER SUSTAINING DEFENDANT TARGET CORPORATION'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND

[*Filed concurrently with Notice of Demurrer; Memorandum of Points and Authorities; Request for Judicial Notice and Proposed Order*]

RESERVATION NO.: R-2242040

Hearing Date	**April 30, 2021**
Hearing Time	**10:00 a.m.**
Location	**Dept. 21**
Complaint Filed:	February 19, 2020
SAC Filed:	January 4, 2021
Trial Date:	None Set

The Court, having considered the Demurrer of Defendant Target Corporation ("Target"), the papers filed in response thereto, all other argument and the record in this case, and for good cause shown:

1. SUSTAINS the Demurrer;

2. Finds Plaintiff's claim against Target, reflected in the First Cause of Action alleging a violation of Health & Safety Code Section 25249.6, *et seq*, fails to state facts sufficient to constitute a case of actions pursuant to Code of Civil Procedure Sections 430.10(e) and 430.30;

3. Orders the Second Amended Complaint DISMISSED WITH PREJUDICE from this action; and

4. Orders judgment to be entered in favor of Target.

IT IS SO ORDERED.

DATED: _____

Hon. Winifred Y. Smith
County of Alameda Superior Court

PROOF OF SERVICE

F.R.C.P. 5 / C.C.P. 1013a(3)/ Rules of Court, Rule 2060

I am a resident of, or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to this action. My business address is: Steptoe & Johnson LLP, 633 West Fifth Street, Suite 1900, Los Angeles, California 90071.

On **February 19, 2021**, I served the following listed document(s), by method indicated below, on the parties in this action: **[PROPOSED] ORDER SUSTAINING DEFENDANT TARGET CORPORATION'S DEMURRER TO SECOND AMENDED COMPLAINT WITHOUT LEAVE TO AMEND**

SERVICE LIST ATTACHED

☐ **BY U.S. MAIL**
By placing □ the original / □ a true copy thereof enclosed in a sealed envelope(s), with postage fully prepaid, addressed as per the attached service list, for collection and mailing at Steptoe & Johnson, LLP 633 West Fifth Street, Suite 1900 in Los Angeles, California 90071, following ordinary business practices. I am readily familiar with the firm's practice for collection and processing of document for mailing. Under that practice, the document is deposited with the United States Postal Service on the same day in the ordinary course of business. Under that practice, the document is deposited with the United States Postal Service on the same day as it is collected and processed for mailing in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY**
By delivering the document(s) listed above in a sealed envelope(s) or package(s) designated by the express service carrier, with delivery fees paid or provided for, addressed as per the attached service list, to a facility regularly maintained by the express service carrier or to an authorized courier or driver authorized by the express service carrier or to an authorized courier or deliver authorized by the express service carrier to receive documents.
Note: Federal Court requirement: service by overnight delivery was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

☐ **BY PERSONAL SERVICE**
□ By personally delivering the document(s) listed above to the offices at the addressee(s) as shown on the attached service list.
□ By placing the document(s) listed above in a sealed envelope(s) and instructing a registered process server to personally delivery the envelope(s) to the offices at the address(es) set forth on the attached service list. The signed proof of service by the registered process server is attached.

☐ **BY ELECTRONIC SERVICE**
(via electronic filing service provider)
By electronically transmitting the document(s) listed above to File & ServeXpress, an electronic filing service provider, at www.fileandservexpress.com . To my knowledge, the transmission was reported as complete and without error. *See* Cal. R. Ct. R. 2.253, 2.255, 2.260.

☒ **BY EMAIL**
(to individual persons)
By electronically transmitting the document(s) listed above to the email address(es) of the person(s) set forth on the attached service list. To my knowledge, the transmission was reported as complete and without error. Service my email was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order. *See* Cal. Rules of Court, rule 2.260.

☐ **BY FACSIMILE**
By transmitting the document(s) listed above from Steptoe & Johnson in Los Angeles, California to the facsimile machine telephone number(s) set forth on the attached service list. Service by facsimile transmission was made ☐ pursuant to agreement of the parties, confirmed in writing, or ☐ as an additional method of service as a courtesy to the parties or ☐ pursuant to Court Order.

I declare under penalty of perjury under the laws of the *State of California* and the *United States of America* that the above is true and correct. Executed on **February 19, 2021,** at Los Angeles, California.

/s/ Carmen Markarian
Carmen Markarian

SERVICE LIST

Center for Environmental Health v. Perrigo Corp., et al.
Case No.: RG20054985

Matter No.: 26550-0005

Mark N. Todzo, Esq. mtodzo@lexlawgroup.com Joseph Mann, Esq. jmann@lexlawgroup.com **LEXINGTON LAW GROUP** 503 Divisadero Street San Francisco, CA 94117 Tel: 415.913.7800 Fax: 415.759.4112	Attorneys for Plaintiff CENTER FOR ENVIRONMENTAL HEALTH
Jeffrey Margulies, Esq. Jeff.margulies@nortonrosefulbright.com Lauren Shoor, Esq. lauren.shoor@nortonrosefulbright.com Andrew Guo, Esq. andy.guo@nortonrosefulbright.com **NORTON ROSE FULBRIGHT US LLP** 555 South Flower Street Forty-First Floor Los Angeles, California 90071 Tel: 213 892 9225 Fax: 213.892.9494	Attorneys for Defendant TARGET CORPORATION
Paul Desrochers, Esq. Paul.desrochers@lewisbrisbois.com **LEWIS BRISBOIS BISGAARD & SMITH LLP** 333 Bush Street, Suite 100 San Francisco, CA 94104 Tel: 415.438.6615 Fax: 415.434.0882	Attorneys for Defendant GRANULES USA, INC.
Cheryl Chang, Esq. chang@blankrome.com Erika Schulz, Esq. eschulz@blankrome.com **BLANKROME LLP** 2029 Century Park East, 6th Fl. Los Angeles, CA 90067 Tel: 424.239.3400 Fax: 424.239.3434	Attorneys for Defendant APOTEX CORP.

Brian Ledger, Esq. bledger@gordonrees.com **GORDON REESE SCULLY MANSUKHANI LLP** 101 W. Broadway, Suite 1600 San Diego, CA 92102-8271 Tel: 619.696.6700 Fax: 619.696.7124	Attorneys for Defendants DR. REDDY'S LABORATORIES, INC. DR. REDDY'S LABORATORIES LOUISIANA, LLP
George Gigounas, Esq. George.gigounas@dlapiper.com Greg Sperla, Esq. Greg.sperla@dlapiper.com **DLA PIPER** 400 Capitol Mall, Suite 2400 Sacramento, CA 95814-4428 Tel: 916.930.3200 Fax: 916.930.3201	Attorneys for Defendants SANOFI-AVENTIS U.S. LLC CHATTEM INC.
Will Wagner, Esq. wagnerw@gtlaw.com **GREENBERG TRAURIG, LLP** 1201 K Street, Suite 1100 Sacramento, CA 95814 Tel: 916.442.1111 Fax: 916.448.1709 Trenton H. Norris trent.norris@arnoldporter Vanessa C. Adriance vanessa.adriance@arnoldporter.com **ARNOLD & PORTER** Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4075 Tel: (415) 471-3303 Fax: (415) 471-3400	Attorneys for Defendant 7-ELEVEN, INC.