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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)

**FILED BY FAX**  
ALAMEDA COUNTY  
January 04, 2021  
CLERK OF  
THE SUPERIOR COURT  
By Shabra Iyamu, Deputy  
CASE NUMBER:  
**RG20054985**

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

#### 4 **INTRODUCTION**

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

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

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

#### 20 **PARTIES**

21 4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("CEH") is a non-profit  
22 corporation dedicated to protecting the public from environmental health hazards and toxic  
23 exposures. CEH is based in Oakland, California and incorporated under the laws of the State of  
24 California. CEH is a "person" within the meaning of Health & Safety Code § 25249.11(a) and  
25 brings this enforcement action in the public interest pursuant to Health & Safety Code §  
26 25249.7(d). CEH is a nationally recognized non-profit environmental advocacy group that has  
27 prosecuted a large number of Proposition 65 cases in the public interest. These cases have  
28 resulted in significant public benefit, including the reformulation of thousands of products to

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

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

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

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

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

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

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

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



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

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

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

11 **BACKGROUND FACTS**

12 20. The People of the State of California have declared by initiative under Proposition  
13 65 their right “[t]o be informed about exposures to chemicals that cause cancer, birth defects, or  
14 other reproductive harm.” Proposition 65, § 1(b).

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

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

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

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

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

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

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

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

24           28.     Any person acting in the public interest has standing to enforce violations of  
25 Proposition 65 provided that such person has supplied the requisite public enforcers with a valid  
26 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the action  
27 within such time. Health & Safety Code § 25249.7(d).

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

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

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

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

3           33. Under Proposition 65, an exposure is “knowing” where the party responsible for  
4 such exposure has:

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

7 27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final  
8 Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2,  
9 § 12601).

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

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

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

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

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

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

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

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

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Dated: January 4, 2021

Respectfully submitted,

LEXINGTON LAW GROUP



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Mark N. Todzo  
Attorneys for Plaintiff  
CENTER FOR ENVIRONMENTAL HEALTH