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CENTER FOR ENVIRONMENTAL HEALTH

ENFORCED  
FILED  
ALAMEDA COUNTY

FEB 19 2020

CLERK OF THE SUPERIOR COURT  
By     K. Ghee     Deputy

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)

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.

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

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

### 19 **JURISDICTION AND VENUE**

20 9. The Court has jurisdiction over this action pursuant to Health & Safety Code §  
21 25249.7, which allows enforcement in any court of competent jurisdiction, and pursuant to  
22 California Constitution Article VI, Section 10, because this case is a cause not given by statute to  
23 other trial courts.

24 10. This Court has jurisdiction over Defendants because each is a business entity that  
25 does sufficient business, has sufficient minimum contacts in California, or otherwise intentionally  
26 avails itself of the California market through the sale, marketing, or use of the Products in  
27 California and/or by having such other contacts with California so as to render the exercise of  
28

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

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

5 **BACKGROUND FACTS**

6 12. The People of the State of California have declared by initiative under Proposition  
7 65 their right “[t]o be informed about exposures to chemicals that cause cancer, birth defects, or  
8 other reproductive harm.” Proposition 65, § 1(b).

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

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

17 14. On October 1, 1987, the State of California officially listed NDMA as a chemical  
18 known to cause cancer. 27 Cal. Code Regs. (“C.C.R.”) § 27001(b). On October 1, 1988, one  
19 year after it was listed as a chemical known to cause cancer, NDMA became subject to the clear  
20 and reasonable warning requirement regarding carcinogens under Proposition 65. 27 C.C.R. §  
21 27001(b); Health & Safety Code § 25249.10(b).

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

26 16. Defendants’ Products contain sufficient quantities of NDMA such that individuals  
27 are exposed to NDMA through the average use of the Products. The primary route of exposure is  
28

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

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

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

12 19. Any person acting in the public interest has standing to enforce violations of  
13 Proposition 65 provided that such person has supplied the requisite public enforcers with a valid  
14 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the action  
15 within such time. Health & Safety Code § 25249.7(d).

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

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

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

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

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

17 24. Under Proposition 65, an exposure is “knowing” where the party responsible for  
18 such exposure has:

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

21 27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final  
22 Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2,  
23 § 12601).

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

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

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

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

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

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

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

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

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

1 33. NDMA is a chemical listed by the State of California as known to cause cancer.  
2 34. Defendants know that ordinary use of the Products will expose users of their  
3 Products to NDMA. Defendants intend that the Products be used in a manner that results in  
4 exposures to NDMA.  
5 35. Defendants have failed, and continue to fail, to provide clear and reasonable  
6 warnings regarding the carcinogenicity of NDMA to users of the Products.  
7 36. By committing the acts alleged above, Defendants have at all times relevant to this  
8 Complaint violated Proposition 65 by knowingly and intentionally exposing individuals to  
9 NDMA without first giving clear and reasonable warnings to such individuals regarding the  
10 carcinogenicity of NDMA.

11 **PRAYER FOR RELIEF**

12 Wherefore, CEH prays for judgment against Defendants as follows:

- 13 1. That the Court, pursuant to Health & Safety Code § 25249.7(a), preliminarily and  
14 permanently enjoin Defendants from offering Products for sale in California without providing  
15 prior clear and reasonable warnings, as CEH shall specify in further application to the Court;
- 16 2. That the Court, pursuant to Health & Safety Code § 25249.7(a), order Defendants  
17 to take action to stop ongoing unwarned exposures to NDMA resulting from use of Products sold  
18 by Defendants, as CEH shall specify in further application to the Court;
- 19 3. That the Court, pursuant to Health & Safety Code § 25249.7(b), assess civil  
20 penalties against each of the Defendants in the amount of \$2,500 per day for each violation of  
21 Proposition 65 according to proof;
- 22 4. That the Court, pursuant to Code of Civil Procedure § 1021.5 or any other  
23 applicable theory, grant CEH its reasonable attorneys' fees and costs of suit; and  
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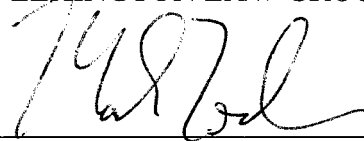
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5. That the Court grant such other and further relief as may be just and proper.

Dated: February 19, 2020

Respectfully submitted,

LEXINGTON LAW GROUP



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Mark N. Todzo  
Attorneys for Plaintiff  
CENTER FOR ENVIRONMENTAL HEALTH