

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

1 **PROOF OF SERVICE**

2

3 I, Alexis Pearson, declare:

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

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

9 **NOTICE OF VIOLATION OF CALIFORNIA SAFE DRINKING WATER AND
10 TOXIC ENFORCEMENT ACT;**

11 **CERTIFICATE OF MERIT; and**

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

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

20 *Please see attached service list.*

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

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

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

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

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

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

1	Stephan R. Passalacqua, District Attorney Sonoma County	Mara W. Elliott, City Attorney City of San Diego
2	600 Administration Drive, Rm. 212J	1200 Third Ave, Suite 700
3	Santa Rosa, CA 95403	San Diego, CA 92101
	jbarnes@sonoma-county.org	CityAttyCrimProp65@sandiego.gov
4	Phillip J. Cline, District Attorney Tulare County	Gregory D. Totten, District Attorney Ventura County
5	221 S. Mooney Avenue, Rm. 224	800 South Victoria Avenue
6	Visalia, CA 93291	Ventura, CA 93009
	Prop65@co.tulare.ca.us	daspecialops@ventura.org
7	Paul E. Zellerbach, District Attorney Riverside County	Gregory Alker, Assistant District Attorney San Francisco County
8	4075 Main Street	732 Brannan Street
9	Riverside, CA 92501	San Francisco, CA 94103
	Prop65@rivcoda.org	gregory.alker@sfgov.org
10	Jeff W. Reisig, District Attorney Yolo County	Anne Marie Schubert, District Attorney Sacramento County
11	301 Second Street	901 G Street
12	Woodland, CA 95695	Sacramento, CA 95814
	cfepd@yolocounty.org	Prop65@sacda.org
13	Dije Ndreu, Deputy District Attorney Monterey County	Eric J. Dobroth, Deputy District Attorney San Luis Obispo County
14	1200 Aguajito Road	County Government Center Annex, 4th Floor
15	Monterey, CA 93940	San Luis Obispo, CA 93408
16	Prop65DA@co.monterey.ca.us	edobroth@co.slo.ca.us
17	Tori Verber Salazar, District Attorney San Joaquin County	Jeffrey S. Rosell, District Attorney Santa Cruz County
18	222 E. Weber Avenue, Room 202	701 Ocean Street
	Stockton, CA 95202	Santa Cruz, CA 95060
19	DAConsumer.Environmental@sjcda.org	Prop65DA@santacruzcounty.us
20	Christopher Dalbey, Deputy District Attorney, Santa Barbara County	Nancy O'Malley, District Attorney Alameda County
21	1112 Santa Barbara Street	7776 Oakport Street, Suite 650
22	Santa Barbara, CA 93101	Oakland, CA 94621
	DAProp65@co.santa-barbara.ca.us	CEPDProp65@acgov.org
23	San Francisco City Attorney's Office City Hall, Room 234	Office of the District Attorney Calaveras County
24	1 Dr. Carlton B. Goodlett Place	891 Mountain Ranch Road
25	Valerie.lopez@sfcityatty.org	San Andreas, CA 95249
26	San Francisco, CA 94102	Prop65Env@co.calaveras.ca.us
27		
28		

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

3 ☐ **BY OVERNIGHT DELIVERY:** I deposited such document(s) in a box or other facility
4 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.

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

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

7
8 
9 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
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Crescent City, CA 95531

District Attorney of El Dorado County
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Placerville, CA 95667

District Attorney of Fresno County
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Fresno, CA 93721

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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

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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

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Hall of Justice
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Los Angeles, CA 90012-3210

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

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San Rafael, CA 94903

District Attorney of Mariposa County
P.O. Box 730
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District Attorney of Mendocino County
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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

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District Attorney of Shasta County
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Fairfield, CA 94533

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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
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Sonora, CA 95370

District Attorney of Yuba County
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Marysville, CA 95901

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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

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