



Environmental Research Center

3111 Camino Del Rio North, Suite 400
San Diego, CA 92108
619-500-3090

August 29, 2019

NOTICE OF VIOLATIONS OF CALIFORNIA HEALTH & SAFETY CODE SECTION 25249.5 *ET SEQ.* (PROPOSITION 65)

Dear Alleged Violator and the Appropriate Public Enforcement Agencies:

I am the Executive Director of Environmental Research Center, Inc. ("ERC"). ERC is a California non-profit corporation dedicated to, among other causes, helping safeguard the public from health hazards by bringing about a reduction in the use and misuse of hazardous and toxic chemicals, facilitating a safe environment for consumers and employees, and encouraging corporate responsibility.

ERC has identified violations of California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), which is codified at California Health & Safety Code §25249.5 *et seq.*, with respect to the products identified below. These violations have occurred and continue to occur because the alleged Violator identified below failed to provide required clear and reasonable warnings with these products. This letter serves as a notice of these violations to the alleged Violator and the appropriate public enforcement agencies. Pursuant to Section 25249.7(d) of the statute, ERC intends to file a private enforcement action in the public interest 60 days after effective service of this notice unless the public enforcement agencies have commenced and are diligently prosecuting an action to rectify these violations.

General Information about Proposition 65. A copy of a summary of Proposition 65, prepared by the Office of Environmental Health Hazard Assessment, is attached with the copy of this letter served to the alleged Violator identified below.

Alleged Violator. The name of the company covered by this notice that violated Proposition 65 (hereinafter the "Violator") is:

Bio-Tech Pharmacal Inc.

Consumer Products and Listed Chemical. The products that are the subject of this notice and the chemical in those products identified as exceeding allowable levels are:

- 1. Bio Tech Pharmacal Inc. EVAC Psyllium Fiber - Lead**
- 2. Bio Tech Pharmacal Inc. D-Mannose - Lead**

On February 27, 1987, the State of California officially listed lead as a chemical known to cause developmental toxicity, and male and female reproductive toxicity. On October 1, 1992, the State of California officially listed lead and lead compounds as chemicals known to cause cancer.

August 29, 2019

Page 2

It should be noted that ERC may continue to investigate other products that may reveal further violations and result in subsequent notices of violations.

Route of Exposure. The consumer exposures that are the subject of this notice result from the recommended use of these products. Consequently, the route of exposure to this chemical has been and continues to be through ingestion.

Approximate Time Period of Violations. Ongoing violations have occurred every day since at least August 29, 2016, as well as every day since the products were introduced into the California marketplace, and will continue every day until clear and reasonable warnings are provided to product purchasers and users or until this known toxic chemical is either removed from or reduced to allowable levels in the products. Proposition 65 requires that a clear and reasonable warning be provided prior to exposure to the identified chemical. The method of warning should be a warning that appears on the product label. The Violator violated Proposition 65 because it failed to provide persons ingesting these products with appropriate warnings that they are being exposed to this chemical.

Consistent with the public interest goals of Proposition 65 and a desire to have these ongoing violations of California law quickly rectified, ERC is interested in seeking a constructive resolution of this matter that includes an enforceable written agreement by the Violator to: (1) reformulate the identified products so as to eliminate further exposures to the identified chemical, or provide appropriate warnings on the labels of these products; (2) pay an appropriate civil penalty; and (3) provide clear and reasonable warnings compliant with Proposition 65 to all persons located in California who purchased the above products in the last three years. Such a resolution will prevent further unwarned consumer exposures to the identified chemical, as well as an expensive and time-consuming litigation.

Please direct all questions concerning this notice to ERC at the above listed address and telephone number.

Sincerely,



Chris Heptinstall
Executive Director
Environmental Research Center

Attachments

Certificate of Merit

Certificate of Service

OEHHA Summary (to Bio-Tech Pharmacal Inc. and its Registered Agent for Service of Process only)

Additional Supporting Information for Certificate of Merit (to AG only)

CERTIFICATE OF MERIT

**Re: Environmental Research Center, Inc.'s Notice of Proposition 65 Violations by Bio-Tech
Pharmaceutical Inc.**

I, Chris Heptinstall, declare:

1. This Certificate of Merit accompanies the attached 60-day notice in which it is alleged the party identified in the notice violated California Health & Safety Code Section 25249.6 by failing to provide clear and reasonable warnings.

2. I am the Executive Director for the noticing party.

3. I have consulted with one or more persons with relevant and appropriate experience or expertise who have reviewed facts, studies, or other data regarding the exposure to the listed chemical that is the subject of the notice.

4. Based on the information obtained through those consultants, 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 that the information did not prove that the alleged Violator will be able to establish any of the affirmative defenses set forth in the statute.

5. Along with the copy of this Certificate of Merit served on the Attorney General is attached additional factual information sufficient to establish the basis for this certificate, including the information identified in California 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.



Dated: August 29, 2019

Chris Heptinstall

CERTIFICATE OF SERVICE PURSUANT TO 27 CCR § 25903

I, the undersigned, declare under penalty of perjury under the laws of the State of California that the following is true and correct:

I am a citizen of the United States and over the age of 18 years of age. My business address is 306 Joy Street, Fort Oglethorpe, Georgia 30742. I am a resident or employed in the county where the mailing occurred. The envelope or package was placed in the mail at Fort Oglethorpe, Georgia.

On August 29, 2019, between 8:00 a.m. and 5:00 p.m. Eastern Time, I served the following documents: **NOTICE OF VIOLATIONS OF CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT; “THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY”** on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to each of the parties listed below and depositing it in a U.S. Postal Service Office with the postage fully prepaid for delivery by Certified Mail:

Current President or CEO
Bio-Tech Pharmacal Inc.
3481 N Highway 112
Fayetteville, AR 72704

Dale Benedict
(Registered Agent for Bio-Tech Pharmacal Inc.)
3481 N Highway 112
Fayetteville, AR 72704

Current President or CEO
Bio-Tech Pharmacal Inc.
PO Box 1927
Fayetteville, AR 72702

On August 29, 2019, between 8:00 a.m. and 5:00 p.m. Eastern Time, I verified the following documents **NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT; ADDITIONAL SUPPORTING INFORMATION FOR CERTIFICATE OF MERIT AS REQUIRED BY CALIFORNIA HEALTH & SAFETY CODE §25249.7(d)(1)** were served on the following party when a true and correct copy thereof was uploaded on the California Attorney General’s website, which can be accessed at <https://oag.ca.gov/prop65/add-60-day-notice> :

Office of the California Attorney General
Prop 65 Enforcement Reporting
1515 Clay Street, Suite 2000
Post Office Box 70550
Oakland, CA 94612-0550

On August 29, 2019, between 8:00 a.m. and 5:00 p.m. Eastern Time, verified the following documents **NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT** were served on the following parties when a true and correct copy thereof was sent via electronic mail to each of the parties listed below:

Nancy O’Malley, District Attorney
Alameda County
7677 Oakport Street, Suite 650
Oakland, CA 94621
CEPDProp65@acgov.org

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

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

Thomas L. Hardy, District Attorney
Inyo County
168 North Edwards Street
Independence, CA 93526
inyoda@inyocounty.us

Notice of Violations of California Health & Safety Code §25249.5 *et seq.*

August 29, 2019

Page 5

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

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

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

Paul E. Zellerbach, District Attorney
Riverside County
3072 Orange Street
Riverside, CA 92501
Prop65@rivcoda.org

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

Mark Ankcorn, Deputy City Attorney
San Diego City Attorney
1200 Third Avenue
San Diego, CA 92101
CityAttyProp65@sandiego.gov

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

Valerie Lopez, Deputy City Attorney
San Francisco City Attorney
1390 Market Street, 7th Floor
San Francisco, CA 94102
Valerie.Lopez@sfcityattys.org

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

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

Bud Porter, Supervising Deputy District Attorney
Santa Clara County
70 W Hedding St
San Jose, CA 95110
EPU@da.sccgov.org

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

Stephan R. Passalacqua, District Attorney
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600 Administration Dr
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jbarnes@sonoma-county.org

Phillip J. Cline, District Attorney
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221 S Mooney Blvd
Visalia, CA 95370
Prop65@co.tulare.ca.us

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

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

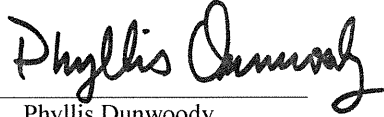
Notice of Violations of California Health & Safety Code §25249.5 *et seq.*

August 29, 2019

Page 6

On August 29, 2019, between 8:00 a.m. and 5:00 p.m. Eastern Time, I served the following documents: **NOTICE OF VIOLATIONS, CALIFORNIA HEALTH & SAFETY CODE §25249.5 *ET SEQ.*; CERTIFICATE OF MERIT** on each of the parties on the Service List attached hereto by placing a true and correct copy thereof in a sealed envelope, addressed to each of the parties on the Service List attached hereto, and depositing it with the U.S. Postal Service with the postage fully prepaid for delivery by First Class Mail.

Executed on August 29, 2019, in Fort Oglethorpe, Georgia.

A handwritten signature in black ink, reading "Phyllis Dunwoody", written over a horizontal line.

Phyllis Dunwoody

Notice of Violations of California Health & Safety Code §25249.5 *et seq.*

August 29, 2019

Page 7

Service List

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

District Attorney, Amador
County
708 Court Street, Suite 202
Jackson, CA 95642

District Attorney, Butte
County
25 County Center Drive, Suite
245
Oroville, CA 95965

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

District Attorney, Del Norte
County
450 H Street, Room 171
Crescent City, CA 95531

District Attorney, El Dorado
County
778 Pacific St.
Placerville, CA 95667

District Attorney, Fresno
County
2220 Tulare Street, Suite 1000
Fresno, CA 93721

District Attorney, Glenn
County
Post Office Box 430
Willows, CA 95988

District Attorney, Humboldt
County
825 5th Street 4th Floor
Eureka, CA 95501

District Attorney, Imperial
County
940 West Main Street, Ste 102
El Centro, CA 92243

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

District Attorney, Kings
County
1400 West Lacey Boulevard
Hanford, CA 93230

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

District Attorney, Los Angeles
County
Hall of Justice
211 West Temple St., Ste 1200
Los Angeles, CA 90012

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

District Attorney, Marin
County
3501 Civic Center Drive,
Room 130
San Rafael, CA 94903

District Attorney, Mariposa
County
Post Office Box 730
Mariposa, CA 95338

District Attorney, Mendocino
County
Post Office Box 1000
Ukiah, CA 95482

District Attorney, Merced
County
550 W. Main Street
Merced, CA 95340

District Attorney, Modoc
County
204 S Court Street, Room 202
Alturas, CA 96101-4020

District Attorney, Mono
County
Post Office Box 617
Bridgeport, CA 93517

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

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

District Attorney, Placer
County
10810 Justice Center Drive,
Ste 240
Roseville, CA 95678

District Attorney, Plumas
County
520 Main Street, Room 404
Quincy, CA 95971

District Attorney, San Benito
County
419 Fourth Street, 2nd Floor
Hollister, CA 95023

District Attorney, San
Bernardino County
303 West Third Street
San Bernadino, CA 92415

District Attorney, San Diego
County
330 West Broadway, Suite
1300
San Diego, CA 92101

District Attorney, San Mateo
County
400 County Ctr., 3rd Floor
Redwood City, CA 94063

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

District Attorney, Sierra
County
100 Courthouse Square, 2nd
Floor
Downieville, CA 95936

District Attorney, Siskiyou
County
Post Office Box 986
Yreka, CA 96097

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

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

District Attorney, Sutter
County
463 2nd Street
Yuba City, CA 95991

District Attorney, Tehama
County
Post Office Box 519
Red Bluff, CA 96080

District Attorney, Trinity
County
Post Office Box 310
Weaverville, CA 96093

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

District Attorney, Yuba
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215 Fifth Street, Suite 152
Marysville, CA 95901

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

San Jose City Attorney's
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200 East Santa Clara Street,
16th Floor
San Jose, CA 95113