State of California - Department of Justice - Attorney General's Office - Proposition 65 Enforcement Reporting

Attention: Prop 65 Coordinator, 1515 Clay Street, Suite 2000, Oakland, CA 94612

FORM JUS 1500 (03-01)

PRIVATE ENFORCEMENT FILING - Health and Safety Code section 25249.7(e) and (f)

REPORT OF CIVIL COMPLAINT FILING

Dlease	print or type required information	☐ Supp	plemental Filing	Corrected Filing		
16430	PLAINTIFF(S)					
ACTION	ENVIRONMENTAL RESEARCH CENTER Plaintiff,	R, a	non-profit	California	corporation,	
	DEFENDANT(S)					
	MEDA CONSUMER HEALTHCARE, INC., a Delaware Corporation; MEDA PHARMACEUTICALS, INC., a Delaware Corporation Defendants.					
	COURT DOCKET NUMBER		COURTNAME	- County Sur	perior Court	
CASE	RG13678826 SHORT CASE NAME		ATAIled	a county but	Jerror Courc	
5 ≥	ENVIRONMENTAL RESEARCH CENT	ER v.	MEDA CONSU	MER HEALTHC	ARE, INC. et al.	
	TYPE OF CLAIM (Check All That Apply)		REL	IEF SOUGHT (Che	eck All That Apply)	
	Propostion 65 Unlawful Discharge		Nw	arning		
E	Proposition 65 Failure to Warn		Discharge Ban			
REPORT	B&P Code section 17200		Civil Penalty			
RE =	Other Preliminary/Permanent Injunction; Attorney Fees					
	Proposition 65 Failure to Warn Discharge Ban So Civil Penalty Preliminary/Permanent Injunction; Attorney Fees COPY OF COMPLAINT MUST BE ATTACHED Copy Copy					
	NAME OF CONTACT Richard Drury / Christina Caro					
	ORGANIZATION				TELEPHONE NUMBER	
FILER	Lozeau Drury LLP ADDRESS				((510)) 836-4200 FAX NUMBER	
	410 12th Street, Suite 250				((510)) 836-4205	
	Oakland, CA 94607	ZIP	E-MAILADE richa	rd@lozeaudr	ury.com	

FILING INSTRUCTIONS: This form can be completed online and printed. If electronic filing is not available, mail the completed form with a copy of the complaint to the attention of the Prop 65 Coordinator at the address shown above. If you need additional space to complete this form please use an attachment.

- 1						
1 2 3 4	RICHARD DRURY (CBN 163559) CHRISTINA M. CARO (CBN 250797) LOZEAU DRURY LLP 410 12 th Street, Suite 250 Oakland, CA 94607 Ph: 510-836-4200 Fax: 510-836-4205 Email: richard@lozeaudrury.com					
5	Email: richard@lozeaudrury.com Attorneys for Plaintiff					
6	ENVIRONMENTAL RESEARCH CENTER					
7						
8						
9	SUPERIOR COURT OF THE STATE OF CALIFORNIA					
10	COUNTY OF ALAMEDA					
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12	ENVIRONMENTAL RESEARCH CENTER,) Case Vo. 13 678 826 a non-profit California corporation,					
13	Plaintiff, COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES					
15	v. Health & Safety Code §25249.5, et seq.					
16	MEDA CONSUMER HEALTHCARE, INC., a Delaware Corporation; MEDA PHARMACEUTICALS, INC., a Delaware Corporation					
18	Defendants.					
20	Plaintiff ENVIRONMENTAL RESEARCH CENTER ("Plaintiff" or "ERC") brings this action in the interests of the general public and, on information and belief, hereby alleges:					
22	INTRODUCTION					
23	1. This action seeks to remedy the continuing failure of Defendants MEDA					
24	CONSUMER HEALTHCARE, INC., a Delaware Corporation ("Meda Consumer"), and					
25 26	MEDA PHARMACEUTICALS, INC., a Delaware Corporation ("Meda Pharmaceuticals")					

(collectively, "Meda" or "Defendants") to warn consumers in California that they are being exposed to lead and/or lead compounds, substances known to the State of California to cause cancer, birth defects and other reproductive harm. Defendants manufacture, package, distribute, market, and/or sell in California the following products containing lead and/or lead compounds (the "PRODUCTS"):

- DrNatura Paranil Jr. Herbal Supplement for Children;
- DrNatura Paranil Liver & Colon Purifying Complex;
- DrNatura Colonix Intestinal Cleanser.
- 2. Lead and lead compounds (hereinafter, the "LISTED CHEMICALS") are substances known to the State¹ of California to cause cancer, birth defects, and other reproductive harm.
- 3. The use and/or handling of the PRODUCTS causes exposures to the LISTED CHEMICALS at levels requiring a "clear and reasonable warning" under California's Safe Drinking Water and Toxic Enforcement Act of 1986, Health & Safety Code ("H&S Code") §25249.5, et seq. ("Proposition 65"). Defendant has failed to provide the health hazard warnings required by Proposition 65.
- 4. Defendants' continued manufacturing, packaging, distributing, marketing and/or sales of the PRODUCTS without the required health hazard warnings causes individuals to be involuntarily and unwittingly exposed to levels of the LISTED CHEMICALS that violate Proposition 65.
- 5. Plaintiff seeks injunctive relief enjoining Defendants from the continued manufacturing, packaging, distributing, marketing and/or sales of the PRODUCTS in California without provision of clear and reasonable warnings regarding the risks of cancer, birth defects and other reproductive harm posed by exposure to the LISTED CHEMICALS through the use and/or handling of the PRODUCTS. Plaintiff seeks an injunctive order

¹ All statutory and regulatory references herein are to California law, unless otherwise specified.

compelling Defendants to bring their business practices into compliance with Proposition 65
by providing a clear and reasonable warning to each individual who has been and who in the
future may be exposed to the LISTED CHEMICALS from the use of the PRODUCTS.
Plaintiff also seeks an order compelling Defendant to identify and locate each individual
person who in the past has purchased the PRODUCTS, and to provide to each such purchaser a
clear and reasonable warning that the use of the PRODUCTS will cause exposures to the
LISTED CHEMICALS.

6. In addition to injunctive relief, Plaintiff seeks an assessment of civil penalties of up to \$2500 per day per violation to remedy Defendants' failure to provide clear and reasonable warnings regarding exposures to the LISTED CHEMICALS.

JURISDICTION AND VENUE

- 7. This Court has jurisdiction over this action pursuant to California Constitution Article VI, Section 10, which grants the Superior Court "original jurisdiction in all causes except those given by statute to other trial courts." The statute under which this action is brought does not specify any other basis for jurisdiction.
- 8. This Court has jurisdiction over Defendants because, based on information and belief, Defendants are businesses having sufficient minimum contacts with California, or otherwise intentionally availing themselves of the California market through the distribution and sale of the PRODUCTS in the State of California, to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.
- 9. Venue in this action is proper in the Alameda Superior Court because the Defendants have violated California law in the County of Alameda.

PARTIES

10. PLAINTIFF Environmental Research Center ("Plaintiff" or "ERC") is a corporation organized under the State of California's Corporations Law. ERC is dedicated to,

among other causes, reducing the use and misuse of hazardous and toxic substances, consumer protection, worker safety and corporate responsibility.

- 11. ERC is a person within the meaning of H&S Code §25118 and brings this enforcement action in the public interest pursuant to H&S Code §25249.7(d).
- 12. Defendant MEDA CONSUMER HEALTHCARE, INC. ("Meda Consumer") is a corporation organized under the State of Delaware's Corporation Law and is a person doing business within the meaning of H&S Code §25249.11.
- 13. Defendant MEDA PHARMACEUTICALS, INC. ("Meda Pharmaceuticals") (collectively with Meda Consumer as "Meda" or "Defendants") is a corporation organized under the State of Delaware's Corporations Law and is a person doing business within the meaning of H&S Code §25249.11.
- 14. Defendants manufacture, package, distribute, market, and/or sell the PRODUCTS for sale or use in California and in Alameda County.

STATUTORY BACKGROUND

- 15. The People of the State of California have declared in Proposition 65 their right "[t]o be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm." Section 1(b) of Initiative Measure, Proposition 65.
- 16. To effect this goal, Proposition 65 requires that individuals be provided with a "clear and reasonable warning" before being exposed to substances listed by the State of California as causing cancer or reproductive toxicity. H&S 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....

17. Proposition 65 provides that any person "violating or threatening to violate" the statute may be enjoined in a court of competent jurisdiction. (H&S Code §25249.7). The phrase "threatening to violate" is defined to mean creating "a condition in which there is a substantial

likelihood that a violation will occur." H&S Code §25249.11(e). Violators are liable for civil penalties of up to \$2,500 per day for each violation of the Act. H&S Code §25249.7.

FACTUAL BACKGROUND

- 18. On February 27, 1987, the State of California officially listed the chemical lead as a chemical known to cause reproductive toxicity. Lead became subject to the warning requirement one year later and was therefore subject to the "clear and reasonable" warning requirements of Proposition 65 beginning on February 27, 1988. 27 California Code of Regulations ("CCR") §25000, et seq.; H&S Code §25249.5, et seq.
- 19. On October 1, 1992, the State of California officially listed the chemicals lead and lead compounds as chemicals known to cause cancer. Lead and lead compounds became subject to the warning requirement one year later and were therefore subject to the "clear and reasonable" warning requirements of Proposition 65 beginning on October 1, 1993. 27 CCR §25000, et seq.; H&S Code §25249.6, et seq. Due to the high toxicity of lead, the maximum allowable dose level for lead is 0.5 ug/day (micrograms a day) for reproductive toxicity.
- 20. To test Defendants' PRODUCTS for lead, Plaintiff hired a well-respected and accredited testing laboratory that designed the testing protocol used and approved by the California Attorney General years ago for testing heavy metals. The results of testing undertaken by Plaintiff of Defendants' PRODUCTS show that the PRODUCTS tested were in violation of the 0.5 ug/day "safe harbor" daily dose limit set forth in Proposition 65's regulations.
- 21. Of particular significance is the fact that people are being exposed to lead through ingestion of Defendants' PRODUCTS as opposed to other, less harmful methods of exposure, such as dermal exposure. Ingestion of lead produces much higher exposure levels and health risks than does dermal exposure to this chemical.
- 22. At all times relevant to this action, Defendants, therefore, have knowingly and intentionally exposed the users and/or handlers of the PRODUCTS to the LISTED

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CHEMICALS without first giving a clear and reasonable warning to such individuals.

- 23. The PRODUCTS have allegedly been sold by Defendants for use in California since at least October 26, 2009. The PRODUCTS continue to be distributed and sold in California without the requisite warning information.
- 24. On October 26, 2012, ERC served Defendants and each of the appropriate public enforcement agencies with a document entitled "Notice of Violations of California Health & Safety Code Section 25249.5" that provided Defendants and the public enforcement agencies with notice that Defendants were in violation of Proposition 65 for failing to warn purchasers and individuals using the PRODUCTS that the use of the PRODUCTS exposes them to lead, a chemical known to the State of California to cause cancer and/or reproductive toxicity ("Prop. 65 Notice") (a copy of the 60-Day Notice is attached hereto as **Exhibit A**).
- 25. As a proximate result of acts by Defendants, persons in the course of doing business within the meaning of Health & Safety Code §25249.11, individuals throughout the State of California, including in the County of Alameda, have been exposed to the LISTED CHEMICALS without a clear and reasonable warning. The individuals subject to the violative exposures include normal and foreseeable users of the PRODUCTS, as well as all other persons exposed to the PRODUCTS.

FIRST CAUSE OF ACTION

(Injunctive Relief for Violations of Health and Safety Code §§ 25249.5, et seq. concerning the PRODUCTS described in the October 26, 2012 Prop. 65 Notice) **Against DEFENDANTS**

- 26. Plaintiff hereby realleges and incorporates by reference all of the above paragraphs as if fully set forth herein.
- 27. On October 26, 2012, Plaintiff sent a 60-Day Notice of Proposition 65 violations to the requisite public enforcement agencies, and to Defendants ("Notice"), attached hereto as Exhibit A. The Notice was issued pursuant to, and in compliance with, the requirements of H&S Code §25249.7(d) and the statute's implementing regulations regarding

the notice of the violations to be given to certain public enforcement agencies and to the violator. The Notice included, *inter alia*, the following information: the name, address, and telephone number of the noticing individual; the name of the alleged violator; the statute violated; the approximate time period during which violations occurred; and descriptions of the violations, including the chemicals involved, the routes of toxic exposure, and the specific product or type of product causing the violations, and was issued as follows:

- a. DEFENDANT and the California Attorney General were provided copies of the Notice by Certified Mail.
- b. DEFENDANT was provided a copy of a document entitled "The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): A Summary," which is also known as Appendix A to Title 27 of CCR §25903.
- c. The California Attorney General was provided with a Certificate of Merit by the attorney for the noticing party, stating that there is a reasonable and meritorious case for this action, and attaching factual information sufficient to establish a basis for the certificate, including the identify of the persons consulted with and relied on by the certifier, and the facts, studies, or other data reviewed by those persons, pursuant to H&S Code §25249.7(h) (2).
- 28. The appropriate public enforcement agencies have failed to commence and diligently prosecute a cause of action under H&S Code §25249.5, et seq. against Defendants based on the allegations herein.
- 29. By committing the acts alleged in this Complaint, Defendants at all times relevant to this action, and continuing through the present, have violated H&S Code §25249.6 by, in the course of doing business, knowingly and intentionally exposing individuals who use or handle the PRODUCTS set forth in the Notice to the LISTED CHEMICALS, without first providing a clear and reasonable warning to such individuals pursuant to H&S Code §§ 25249.6 and 25249.11(f).
 - 30. By the above-described acts, Defendants have violated H&S Code § 25249.6

and is therefore subject to an injunction ordering Defendants to stop violating Proposition 65, to provide warnings to all present and future customers, and to provide warnings to Defendants' past customers who purchased or used the PRODUCTS without receiving a clear

- An action for injunctive relief under Proposition 65 is specifically authorized by
- Continuing commission by Defendants of the acts alleged above will irreparably harm the citizens of the State of California, for which harm they have no plain, speedy, or

Wherefore, Plaintiff prays for judgment against Defendants, as set forth hereafter.

SECOND CAUSE OF ACTION

(Civil Penalties for Violations of Health and Safety Code § 25249.5, et seq. concerning the PRODUCTS described in PLAINTIFF's NOTICE **Against DEFENDANTS**)

- Plaintiff hereby realleges and incorporates by reference all of the above
- By committing the acts alleged in this Complaint, Defendants at all times relevant to this action, and continuing through the present, have violated H&S Code §25249.6 by, in the course of doing business, knowingly and intentionally exposing individuals who use or handle the PRODUCTS set forth in the Notice to the LISTED CHEMICALS, without first providing a clear and reasonable warning to such individuals pursuant to H&S Code §§ 25249.6 and
- By the above-described acts, Defendants are liable, pursuant to H&S Code §25249.7(b), for a civil penalty of \$2,500 per day per violation for each unlawful exposure to the

Wherefore, Plaintiff prays judgment against Defendants, as set forth hereafter.

THE NEED FOR INJUNCTIVE RELIEF

- 36. Plaintiff hereby realleges and incorporates by reference all of the above paragraphs as if fully set forth herein.
- 37. By committing the acts alleged in this Complaint, Defendants have caused irreparable harm for which there is no plain, speedy or adequate remedy at law. In the absence of equitable relief, Defendants will continue to create a substantial risk of irreparable injury by continuing to cause consumers to be involuntarily and unwittingly exposed to the LISTED CHEMICALS through the use and/or handling of the PRODUCTS.

PRAYER FOR RELIEF

Wherefore, Plaintiff accordingly prays for the following relief:

- A. A preliminary and permanent injunction, pursuant to H&S Code §25249.7(b), enjoining Defendants, their agents, employees, assigns and all persons acting in concert or participating with Defendants, from distributing or selling the PRODUCTS in California without first providing a clear and reasonable warning, within the meaning of Proposition 65, that the users and/or handlers of the PRODUCTS are exposed to the LISTED CHEMICALS.
- B. An injunctive order, pursuant to H&S Code §25249.7(b), compelling Defendants to identify and locate each individual who has purchased the PRODUCTS since October 26, 2009, and to provide a warning to such person that the use of the PRODUCTS will expose the user to chemicals known to cause cancer, birth defects, and other reproductive harm.
- C. An assessment of civil penalties pursuant to Health & Safety Code §25249.7(b), against Defendants in the amount of \$2,500 per day for each violation of Proposition 65;
- D. An award to Plaintiff of its reasonable attorneys fees and costs of suit pursuant to California Code of Civil Procedure §1021.5, as Plaintiff shall specify in further application to the Court; and,
 - E. Any such other and further relief as may be just and proper.

1	DATED: May <u>8</u> , 2013	LOZEAU Į DŖURY LLP
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4		Richard T. Drury Christina M. Caro
5		Attorneys for Plaintiff Environmental Research Center
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EXHIBIT A



7 510.836.4200 € 510.836.4205 410 12th Street, Suite 250 Oakfand, Ca 94607 www.lozeaudrury.com mckand@kozeaudrury.com

VIA CERTIFIED MAIL

Current CEO or President Meda Consumer Healthcare, Inc. 200 North Cobb Parkway Suite 428 Marietta, GA 30067

Corporation Trust Company (Meda Consumer Healthcare, Inc.'s Registered Agent for Service of Process) Corporation Trust Center 1209 Orange Street Wilmington, DE 19801

Current CEO or President Meda Pharmaceuticals, Inc. 265 Davidson Avenue Suite 400 Somerset, NJ 08873-4120

Corporation Trust Company
(Meda Pharmaceuticals, Inc.'s Registered
Agent for Service of Process)
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

CT Corporation System (Meda Pharmaceuticals, Inc.'s Registered Agent for Service of Process in California) 818 W. Seventh Street Los Angeles, CA 90017

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

VIA PRIORITY MAIL

District Attorneys of All California Counties and Select City Attorneys (See Attached Certificate of Service)

Re: Notice of Violations of California Health & Safety Code Section 25249.5 et seq.

Dear Addressees:

I represent the Environmental Research Center ("ERC") in connection with this Notice of Violations of California's Safe Drinking Water and Toxic Enforcement Act of 1986, which is

codified at California Health & Safety Code Section 25249.5 et seq. and also referred to as Proposition 65.

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.

The names of the Companies covered by this notice that violated Proposition 65 (hereinafter "the Violators") are:

Meda Consumer Healthcare, Inc. Meda Pharmaceuticals, Inc.

The products that are the subject of this notice and the chemicals in those products identified as exceeding allowable levels are:

DrNatura Paranil Jr. Herbal Supplement for Children - Lead

DrNatura Paranil Liver & Colon Purifying Complex - Lead

DrNatura Colonix Intestinal Cleanser - 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.

This letter is a notice to each of the Violators and the appropriate governmental authorities of the Proposition 65 violations concerning the listed products. This notice covers all violations of Proposition 65 involving the Violators currently known to ERC from the information now available. ERC may continue to investigate other products that may reveal further violations. A summary of Proposition 65, prepared by the Office of Environmental Health Hazard Assessment, is enclosed with the copy of this letter to each of the Violators.

Each of the Violators has manufactured, marketed, distributed, and/or sold the listed products, which have exposed and continue to expose numerous individuals within California to the identified chemicals. The consumer exposures that are the subject of this notice result from the purchase, acquisition, handling and/or recommended use of these products by consumers. The primary route of exposure to these chemicals has been through ingestion, but may have also occurred through inhalation and/or dermal contact. Proposition 65 requires that a clear and reasonable warning be provided prior to exposure to the identified chemicals. The method of warning should be a warning that appears on the product's label. Each of the Violators violated Proposition 65 because they failed to provide an appropriate warning to persons using and/or handling these products that they are being exposed to the identified chemicals. Each of these

ongoing violations has occurred on every day since October 26, 2009, as well as every day since the products were introduced in the California marketplace, and will continue every day until clear and reasonable warnings are provided to product purchasers and users.

Pursuant to Section 25249.7(d) of the statute, ERC intends to file a citizen enforcement action sixty days after effective service of this notice unless each of the Violators agrees in an enforceable written instrument to: (1) reformulate the listed products so as to eliminate further exposures to the identified chemicals; and (2) pay an appropriate civil penalty. Consistent with the public interest goals of Proposition 65 and my client's objectives in pursuing this notice, ERC is interested in seeking a constructive resolution to this matter. Such resolution will avoid both further unwarned consumer exposures to the identified chemicals and expensive and time consuming litigation.

ERC's Executive Director is Chris Heptinstall, and is located at 3111 Camino Del Rio North, Suite 400, San Diego, CA 92108; Tel. 619-500-3090. ERC has retained me in connection with this matter. We suggest that communications regarding this Notice of Violations should be directed to my attention at the above listed law office address and telephone number.

Sincerely,

Richard Drary

Attachments

Certificate of Merit Certificate of Service

OEHHA Summary (to Meda Consumer Healthcare, Inc., Meda Pharmaceuticals, Inc., and their Registered Agents for Service of Process only)

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

CERTIFICATE OF MERIT

Re: Environmental Research Center's Notice of Proposition 65 Violations by Meda Consumer Healthcare, Inc. and Meda Consumer Pharmaceuticals, Inc.

I, Richard Drury, declare:

- This Certificate of Merit accompanies the attached sixty-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 an attorney 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 violators 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: October 26, 2012

Richard Doory

CERTIFICATE OF SERVICE

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, over the age of 18 years of age, and am not a party to the within entitled action. 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 October 26, 2012, 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 the party listed below and depositing it in a US Postal Service Office with the postage fully prepaid for delivery by Certified Mail:

Current CEO or President

Meda Consumer Healthcare, Inc.

200 North Cobb Parkway

Suite 428

Marietta, GA 30067

Corporation Trust Company

(Meda Consumer Healthcare, Inc.'s Registered Agent

for Service of Process) Corporation Trust Center 1209 Orange Street Wilmington, DE 19801

Current CEO or President Meda Pharmaceuticals, Inc. 265 Davidson Avenue

Suite 400

Somerset, NJ 08873-4120

Corporation Trust Company

(Meda Pharmaceuticals, Inc.'s Registered Agent

for Service of Process) Corporation Trust Center 1209 Orange Street Wilmington, DE 19801

CT Corporation System

(Meda Pharmaceuticals, Inc.'s Registered Agent

for Service of Process in California)

818 W. Seventh Street Los Angeles, CA 90017

On October 26, 2012, I served the following documents: NOTICE OF VIOLATION, 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) on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below and depositing it in a US Postal Service Office with the postage fully prepaid for delivery by Certified Mail:

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

On October 26, 2012, I served the following documents: NOTICE OF VIOLATION, 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 Priority Mail.

Executed on October 26, 2012, in Fort Oglethorpe, Georgia.

Amber Schaub

Page 7

District Attorney, Alameda County 1225 Fallon Street, Suite 900 Oakland, CA 94612

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

District Atterney, 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, Calaveras County 891 Mountain Ranch Road San Andreas, CA 95249

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

District Attorney, Contra Costa County 900 Ward Street Martinez, CA 94553

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

District Attorney, El Dorado County 515 Main Street 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 Atterney, Humboldt County 825 5th Street 4^a Floor Eureka, CA 95501

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

District Attorney, Inyo County 230 W. Line Street Bishop, CA 93514

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, Lassen County 220 South Lassen Street, Ste. 8 Susanville, CA 96130

Service List

District Attorney, Los Angeles County 210 West Temple Street, Suite 18000 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, Mendecino County Post Office Box 1000 Ukish, 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, Monterey County Post Office Box 1131 Salinas, CA 93902

District Attorney, Napa County 931 Parkway Mall Napa, CA 94559

District Attorney, Nevada County 110 Union 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 92678

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

District Attorney, Riverside County 3960 Orange Street Riverside, CA 92501

District Attorney, Sacramento County 901 "G" Street Sacramento, CA 95814

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

District Attorney, San Bernardino County 316 N. Mountain View Avenue San Bernardino, CA 92415-0004 District Attorney, San Diego County 330 West Broadway, Suite 1300 San Diego, CA 92101

District Attorney, San Francisco County 850 Bryant Street, Suite 322 San Francsico, CA 94103

District Attorney, San Joaquin County 222 E. Weber Ave, Rm. 202 Stockton, CA 95202

District Attorney, San Luis Obispo County 1035 Palm St, Room 450 San Luis Obispo, CA 93408

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

District Attorney, Santa Barbara County 1112 Santa Barbara Street Santa Barbara, CA 93101

District Attorney, Santa Clara County 70 West Hedding Street San Jose, CA 95110

District Attorney, Santa Cruz County 701 Ocean Street, Room 200 Santa Cruz, CA 95060

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

District Attorney, Sierra County PO Box 457 Downleville, CA 95936

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

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

District Attorney, Sonoma County 600 Administration Drive, Room 2123 Santa Rosa, CA 95403

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

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

District Atterney, Tehama County Post Office Box 519 Red Hluff, CA 96080

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

District Attorney, Tulare County 221 S. Mooney Blvd., Room 224 Visalia, CA 93291 District Attorney, Tuolumne County 423 N. Washington Street Sonora, CA 95370

District Attorney, Ventura County 800 South Victoria Ave, Suite 314 Ventura, CA 93009

District Attorney, Yolo County 301 2^{x1} Street Woodland, CA 95695

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THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY

The following summary has been prepared by the Office of Environmental Health Hazard Assessment, the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as "Proposition 65"). A copy of this summary must be included as an attachment to any notice of violation served upon an alleged violator of the Act. The summary provides basic information about the provisions of the law, and is intended to serve only as a convenient source of general information. It is not intended to provide authoritative guidance on the meaning or application of the law. The reader is directed to the statute and its implementing regulations (see citations below) for further information. Proposition 65 appears in California law as Health and Safety Code Sections 25249.5 through 25249.13. Regulations that provide more specific guidance on compliance, and that specify procedures to be followed by the State in carrying out certain aspects of the law, are found in Title 22 of the California Code of Regulations, Sections 12000 through 14000.

WHAT DOES PROPOSITION 65 REQUIRE?

The "Governor's List." Proposition 65 requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, or birth defects or other reproductive harm. This list must be updated at least once a year. Over 550 chemicals have been listed as of May 1, 1996. Only those chemicals that are on the list are regulated under this law. Businesses that produce, use, release or otherwise engage in activities involving those chemicals must comply with the following: Clear and reasonable warnings. A business is required to warn a person before "knowingly and intentionally" exposing that person to a listed chemical. The warning given must be "clear and reasonable." This means that the warning must: (1) clearly make known that the chemical involved is known to cause cancer, or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed. Exposures are exempt from the warning requirement if they occur less than twelve months after the date of listing of the chemical. Prohibition from discharges into drinking water. A business must not knowingly discharge or release a listed chemical into water or onto land where it passes or probably will pass into a source of drinking water. Discharges are exempt from this requirement if they occur less than twenty months after the date of listing of the chemical.

DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. The law exempts:

Governmental agencies and public water utilities. All agencies of the federal, State or local government, as well as entities operating public water systems, are exempt. Businesses with nine or fewer employees. Neither the warning requirement nor the discharge prohibition applies to a business that employs a total of nine or fewer employees.

Exposures that pose no significant risk of cancer. For chemicals that are listed as known to the State to cause cancer ("carcinogens"), a warning is not required if the business can demonstrate that the exposure occurs at a level that poses "no significant risk." This means that the exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. The Proposition 65 regulations identify specific "no significant risk" levels for more than 250 listed carcinogens. Exposures that will produce no observable reproductive effect at 1,000 times the level in question. For chemicals known to the State to cause birth defects or other reproductive harm ("reproductive toxicants"), a warning is not required if the business can demonstrate that the exposure will produce no observable effect, even at 1,000 times the level in question. In other words,

the level of exposure must be below the "no observable effect level (NOEL)," divided by a 1,000-fold safety or uncertainty factor. The "no observable effect level" is the highest dose level which has not been associated with an observable adverse reproductive or developmental effect. Discharges that do not result in a "significant amount" of the listed chemical entering into any source of drinking water. The prohibition from discharges into drinking water does not apply if the discharger is able to demonstrate that a "significant amount" of the listed chemical has not, does not, or will not enter any drinking water source, and that the discharge complies with all other applicable laws, regulations, permits, requirements, or orders. A "significant amount" means any detectable amount, except an amount that would meet the "no significant risk" or "no observable effect" test if an individual were exposed to such an amount in drinking water.

HOW IS PROPOSITION 65 ENFORCED?

Enforcement is carried out through civil lawsuits. These lawsuits may be brought by the Attorney General, any district attorney, or certain city attorneys (those in cities with a population exceeding 750,000). Lawsuits may also be brought by private parties acting in the public interest, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation. The notice must provide adequate information to allow the recipient to assess the nature of the alleged violation. A notice must comply with the information and procedural requirements specified in regulations (Title 22, California Code of Regulations, Section 12903). A private party may not pursue an enforcement action directly under Proposition 65 if one of the governmental officials noted above initiates an action within sixty days of the notice. A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court of law to stop committing the violation.

FOR FURTHER INFORMATION...

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900.