

CLIFFWOOD LAW FIRM, PC

12100 WILSHIRE BLVD, SUITE 800
LOS ANGELES, CALIFORNIA 90025
(310)200-3227

60-DAY NOTICE OF INTENT TO SUE

for violations of the Safe Drinking Water and Toxic Enforcement Act of 1986

July 8, 2024

Current President/CEO
Swiss-American CDMO, LLC
c/o C T Corporation System
1999 Bryan St., Ste. 900
Dallas, TX, 75201-3136

Current President/CEO
Elta MD Holdings, Inc.
c/o The Corporation Trust Company, Agent
1209 Orange St
Wilmington, DE 19801

Current President/CEO
Elta MD, Inc.
Attn: Legal Dept.
4110 N. Scottsdale Rd., Suite 300
Scottsdale, AZ 85251

Current President or CEO
Aesthetica Cosmetic Surgery & Laser Center
Attn: Legal Dept.
19500 Sandridge Way, Suite 350
Leesburg, VA 20176

Re: NOTICE OF VIOLATION AGAINST SWISS-AMERICAN CDMO, LLC, ELTA MD, INC., ELTA MD HOLDINGS, INC., AESTHETICA COSMETIC SURGERY & LASER CENTER, of CALIFORNIA HEALTH & SAFETY CODE SECTION 25249.6

To Whom It May Concern and to Public Prosecutors:

We represent Initiative for Safer Cosmetics (“IFSC”), an organization in the State of California acting in the interest of the general public. This letter serves as notice that the parties listed above are in violation of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, commencing with section 25249.5 of the Health and Safety Code (“Proposition 65”). In particular, the violations alleged by this notice consist of types of harm that may potentially result from exposures to the toxic chemical Diethanolamine (“DEA”). This chemical was listed as a carcinogen on June 22, 2012.

The specific type of product that is causing exposures in violation of Proposition 65 is Body Cream, including but not limited to:

| Product Name | Violative Chemical | Violators |
|---|-------------------------|---|
| EltaMD Skin Restore Body Cream UPC: 090205025601 | Diethanolamine (DEA) | Swiss-American CDMO, LLC Elta MD, Inc. Elta MD Holdings, Inc. Aesthetica Cosmetic Surgery & Laser Center |

The routes of exposure for the violations include inhalation by consumers. These exposures occur through the reasonably foreseeable use of the product. The sales of this product have been occurring since at least June 7, 2024, are continuing to this day and will continue to occur as long as the product subject to this notice is sold to and used by consumers.

Proposition 65 requires that a clear and reasonable warning is provided with these products regarding the exposures to DEA caused by ordinary use of the product. The Parties are in violation of Proposition 65 by failing to provide such warning to consumers and as a result of the sales of this product, exposures to DEA have been occurring without proper warnings.

Pursuant to Proposition 65, notice and intent to sue shall be provided to violators 60 days before filing a complaint. This letter provides notice of the alleged violation to the parties listed above and the appropriate governmental authorities. A summary of Proposition 65 is attached.

IFSC identifies Dekee Yangzom as a responsible individual within the entity; 2934 1/2 Beverly Glen Blvd., Suite 46, Los Angeles, CA 90077; 310-892-5658. Ms. Yangzom requests all communications be directed to IFSC's attorneys.

Please direct all communication regarding this notice to IFSC's attorney, Elham Shabatian (ellie@cliffwoodlaw.com), Cliffwood Law Firm PC, 12100 Wilshire Blvd., Suite 800, Los Angeles, CA 90025, 310-200-3227.

Sincerely,



Elham Shabatian
CLIFFWOOD LAW FIRM, PC
Cc: see attached distribution list

Attachments:

1. Certificate of Merit;
2. Certificate of Service;
3. Appendix "A" - "The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): A Summary" (to the Noticed Parties only);
4. Certificate of Merit (Attorney General Copy); Factual information sufficient to establish the basis of the certificate of merit (only sent to Attorney General)

CERTIFICATE OF MERIT

Health and Safety Code Section 25249.7(d)

Re: Initiative for Safer Cosmetics' (IFSC) Notice of Proposition 65 Violations by Swiss-American CDMO, LLC, Elta MD, Inc., Elta MD Holdings, Inc., Aesthetica Cosmetic Surgery & Laser Center

I, Elham Shabatian, attorney at law, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged the parties identified in the notice have violated Health and Safety Code section 25249.6 by failing to provide clear and reasonable warnings.

2. I am the 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, and/or other data regarding the alleged exposures to the listed chemical that is the cause of action.

4. Based on the information obtained through those consultations, and on all 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 plaintiffs' case can be established and 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. The copy of this 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 and Safety Code section 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: July 8, 2024

By  _____
Elham Shabatian

PROOF OF SERVICE

I, Elham Shabatian, am over the age of 18 and am not a party to this case. I am a resident of or employed in the county where the mailing occurred. My business address is 12100 Wilshire Blvd, Suite 800, Los Angeles, CA 90025

On July 8, 2024, I served the following documents:

1. 60-Day Notice of Intent to Sue Under Health and Safety Code section 25249.6
2. Certificate of Merit; Health and Safety Code Section 25249.7 (d)
3. Certificate of Merit (Attorney General Copy); Factual information sufficient to establish the basis of the certificate of merit (*only sent to Attorney General*)
4. The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): A Summary

on the alleged violator (s) listed below via First Class Mail through the United States Postal Service by placing a true and correct copy in a sealed envelope, addressed to the entity listed below and providing such envelope to a United States Postal Service Representative:

| | | | |
|---|---|---|--|
| Current President/CEO Swiss-American CDMO, LLC c/o C T Corporation System 1999 Bryan St., Ste. 900 Dallas, TX, 75201-3136 | Current President/CEO Elta MD, Inc. Attn: Legal Dept. 4110 N. Scottsdale Rd., Suite 300 Scottsdale, AZ 85251 | Current President/CEO Elta MD Holdings, Inc. c/o The Corporation Trust Company, Agent 1209 Orange St Wilmington, DE 19801 | Current President or CEO Aesthetica Cosmetic Surgery & Laser Center Attn: Legal Dept. 19500 Sandridge Way, Suite 350 Leesburg, VA 20176 |
|---|---|---|--|

as well as by filing electronically a true and correct copy thereof as permitted through the website of the California Office of the Attorney General via link at oag.ca.gov/prop65:

State of California Department of Justice
Office of the Attorney General of California
Filing link: oag.ca.gov/prop65

Copies of the notice were provided to the public enforcers by placing a true and correct copy thereof in a sealed envelope, addressed to each of the District Attorney and City Attorney offices the parties listed on the attached Distribution List. The District Attorney and City Attorney offices that have requested electronic service only were served electronically via the email addresses listed on the Distribution List.

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

Signature



Elham Shabatian

July 8, 2024

DISTRIBUTION LIST

| | | |
|---|---|--|
| District Attorney Alpine County PO Box 248 Markleeville, CA 96120 | District Attorney Lake County 255 North Forbes Street Lakeport, CA 95453 | District Attorney Sierra County PO Box 457 Downieville, CA 95936 |
| District Attorney Amador County 708 Court Street, Suite 202 Jackson, CA 95642 | District Attorney Los Angeles County Hall of Justice 211 W. Temple St. Ste 1200 Los Angeles, CA 90012 | District Attorney's Office Siskiyou County Courthouse 311 Fourth Street, Room 204 Yreka, CA 96097 |
| District Attorney Butte County 25 County Center Drive, Suite 245 Oroville, CA 95965 | District Attorney Madera County 209 West Yosemite Avenue Madera, CA 93637 | District Attorney Solano County 675 Texas Street, Ste 4500 Fairfield, CA 94533 |
| District Attorney Colusa County 310 6th Street Colusa, CA 95932 | District Attorney Marin County 3501 Civic Center Drive, Room 130 San Rafael, CA 94903 | District Attorney Stanislaus County 832 12th Street, Ste 300 Modesto, CA 95354 |
| District Attorney Del Norte County 450 H Street, Suite 171 Crescent City, CA 95531 | District Attorney Mendocino County PO Box 1000 Ukiah, CA 95482 | District Attorney Sutter County 446 Second Street Yuba City, CA 95991 |
| District Attorney EL Dorado County 778 Pacific Street Placerville, CA 95667 | District Attorney Modoc County 204 S Court Street, Room 202 Alturas, CA 96101-4020 | District Attorney Tehama County PO Box 519 Red Bluff, CA 96080 |
| District Attorney Mono County Post Office Box 617 Bridgeport, CA 93517 | District Attorney Orange County 300 N Flower St. Santa Ana, CA 92703 | District Attorney Trinity County Post Office Box 310 Weaverville, CA 96093 |
| District Attorney Glenn County Post Office Box 430 Willows, CA 95988 | District Attorney San Benito County 419 4th Street Hollister, CA 95023 | District Attorney Tuolumne County 423 North Washington St. Sonora, CA 95370 |
| District Attorney Humboldt County 825 5th Street 4th Floor Eureka, CA 95501 | District Attorney San Bernardino County 316 No. Mountain View Avenue San Bernardino, CA 92415 | District Attorney Yuba County 215 Fifth Street, Suite 152 Marysville, CA 95901 |
| District Attorney Imperial County 940 West Main Street, Suite 102 El Centro, CA 92243 | District Attorney San Mateo County 400 County Ctr., 3rd Floor Redwood City, CA 94063 | Los Angeles City Attorney's Office City Hall East 200 N. Main St., Suite 800 Los Angeles, CA 90012 |
| District Attorney Kern County 1215 Truxtun Avenue Bakersfield, CA 93301 | District Attorney Shasta County 1355 West Street Redding, CA 96001 | District Attorney Kings County 1400 West Lacey Blvd. Hanford, CA 93230 |
| Alameda County District Attorney CEPDProp65@acgov.org | Calaveras County District Attorney Prop65Env@co.calaveras.ca.us | Contra Costa County District Attorney sgrassini@contracostada.org |
| Inyo County District Attorney inyoda@inyocounty.us | Lassen County District Attorney mlatimer@co.lassen.ca.us | Mariposa County District Attorney mcda@mariposacounty.org |
| Merced County District Attorney Prop65@countyofmerced.com | Monterey County District Attorney Prop65DA@co.monterey.ca.us | Napa County District Attorney CEPD@countyofnapa.org |
| Nevada County District Attorney DA.Prop65@co.nevada.ca.us | Placer County District Attorney Prop65@placer.ca.gov | Plumas County District Attorney davidhollister@countyofplumas.com |
| Riverside County District Attorney Prop65@rivcoda.org | Sacramento County District Attorney Prop65@sacda.org | San Diego City Attorney CityAttyProp65@sandiego.gov |
| San Diego County District Attorney SanDiegoDAProp65@sdca.org | San Francisco County District Attorney alexandra.grayner@sfgov.org | San Francisco City Attorney Valerie.Lopez@sfcityattorney.org |
| San Joaquin County District Attorney DA DAConsumer.Environmental@sjcda.org | San Luis Obispo County District Attorney edobroth@co.slo.ca.us | Santa Barbara County District Attorney DAProp65@co.santa-barbara.ca.us |
| Santa Clara County District Attorney EPU@da.sccgov.org | Santa Cruz County District Attorney Prop65DA@santacruzcounty.us | Sonoma County District Attorney jbarnes@sonoma-county.org |
| Tulare County District Attorney Prop65@co.tulare.ca.us | Ventura County District Attorney daspecialops@veutura.org | Yolo County District Attorney cfepd@yolocounty.org |
| San Jose City Attorney's Office proposition65notices@sanjoseca.gov | District Attorney Fresno consumerprotection@fresnocountyca.gov | District Attorney of Roseville pwp65@place.ca.gov |

APPENDIX A

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT CALIFORNIA PROTECTION AGENCY THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACTION

1986 (PROPOSITION 65): A SUMMARY

The following summary has been prepared by the office of Environmental Health Hazard Assessment, the Lead and Toxic Enforcement Act 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 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 27 of the California Code Regulations, Sections 250000 through 270000.

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 725 chemicals have been listed as of November 16, 2001. 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 the 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 the listing of chemicals.

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.

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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.

Discharge that does 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 list 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; expect 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 27, California Code of Regulations, Section 25903). 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 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