

LITIGATION AND TRIAL LAW

Kevin J. Cole, Esq.
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March 2, 2020

VIA CERTIFIED MAIL

Black Diamond Supplements, LLC
c/o Brian Gamaly (Agent for Service of Process)
7120 E. Indian School Rd., Ste E.
Scottsdale, AZ 85255

Re: **60-Day Notice of Proposition 65 Violation (California Health & Safety Code § 25249 et seq.)**

Dear Mr. Gamaly:

We represent Zachary Stein, a citizen of the State of California acting in the interest of the general public. This letter serves as notice that Black Diamond Supplements, LLC (“Black Diamond”) is in violation of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, commencing with Section 25249.6 of the Health and Safety Code (“Proposition 65”).

Black Diamond is selling products that the State of California has identified to contain carcinogenic properties without the labeling required by Proposition 65. In particular, your sale of “Monster Plexx by Innovative Labs” (the “Subject Product”) (<https://blackdiamondsupplements.com/shop/monster-plexx/>) violates Proposition 65 because the Subject Product contains 4-Androstene-3b-ol,17-one (commonly marketed as “4-Androsterone” or “4-DHEA”), which converts to Androstenedione when ingested in the human body. The sale of products that convert to Androstenedione requires warning labels in the State of California.

As recognized by the State of California, Androstenedione is a cancer-causing toxic substance. *See* Proposition 65, *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity* (Jan. 3, 2020), available at <https://oehha.ca.gov/media/downloads/proposition-65/p65list010320.pdf>. Androstenedione was added to the list of chemicals known to cause cancer on May 3, 2011. *See id.*

California residents who consume the Subject Product are exposed to Androstenedione through direct ingestion. These exposures occur through the reasonably foreseeable use (i.e., ingestion) of any product containing Androstenedione, such as the Subject Product. Black Diamond has been selling the Subject Product since at least December 10, 2017. Therefore, Black Diamond has exposed consumers to Androstenedione in violation of Proposition 65 for over two years and two months. These violations will continue to occur as long as the Subject Product is sold to and used by consumers.

Proposition 65 requires that a clear and reasonable warning be provided with any product that exposes consumers to Androstenedione through its ordinary use. *See* Cal. Health & Saf. Code, § 25249.6. Black Diamond is in violation of Proposition 65 by failing to provide the required Proposition 65 warning to consumers. As a result of the sales of this product, exposures to Androstenedione have been occurring without proper warnings.

Proposition 65 requires that 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 Black Diamond and the appropriate governmental authorities. A summary of Proposition 65 is attached as Appendix A.

If you have any questions or wish to discuss any of the above, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kevin J. Cole', with a stylized, cursive script.

Kevin J. Cole

Enclosures

APPENDIX A

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

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

The following summary has been prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), 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 OEHHA implementing regulations (see citations below) for further information.

FOR INFORMATION CONCERNING THE BASIS FOR THE ALLEGATIONS IN THE NOTICE RELATED TO YOUR BUSINESS, CONTACT THE PERSON IDENTIFIED ON THE NOTICE.

The text of Proposition 65 (Health and Safety Code Sections 25249.5 through 25249.13) is available online at: <http://oehha.ca.gov/prop65/law/P65law72003.html>. 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 of Regulations, sections 25102 through 27001.¹ These implementing regulations are available online at: <http://oehha.ca.gov/prop65/law/P65Regs.html>.

WHAT DOES PROPOSITION 65 REQUIRE?

The “Proposition 65 List.” Under Proposition 65, the lead agency (OEHHA) publishes a list of chemicals that are known to the State of California to cause cancer and/or reproductive toxicity. Chemicals are placed on the Proposition 65 list if they are known to cause cancer and/or birth defects or other reproductive harm, such as damage to

¹ All further regulatory references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated. The statute, regulations and relevant case law are available on the OEHHA website at: <http://www.oehha.ca.gov/prop65/law/index.html>.

female or male reproductive systems or to the developing fetus. This list must be updated at least once a year. The current Proposition 65 list of chemicals is available on the OEHHA website at: http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html.

Only those chemicals that are on the list are regulated under Proposition 65. Businesses that produce, use, release or otherwise engage in activities involving listed 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 unless an exemption applies. 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 to that chemical. Some exposures are exempt from the warning requirement under certain circumstances discussed below.

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. Some discharges are exempt from this requirement under certain circumstances discussed below.

DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. You should consult the current version of the statute and regulations (<http://www.oehha.ca.gov/prop65/law/index.html>) to determine all applicable exemptions, the most common of which are the following:

Grace Period. Proposition 65 warning requirements do not apply until 12 months after the chemical has been listed. The Proposition 65 discharge prohibition does not apply to a discharge or release of a chemical that takes place less than 20 months after the listing of the chemical.

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. This includes all employees, not just those present in California.

Exposures that pose no significant risk of cancer. For chemicals that are listed under Proposition 65 as known to the State to cause cancer, a warning is not required if the business causing the exposure 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” (NSRLs) for many listed carcinogens. Exposures below these levels are exempt from the warning requirement. See OEHHA's website at: <http://www.oehha.ca.gov/prop65/getNSRLs.html> for a list of NSRLs, and Section 25701 *et seq.* of the regulations for information concerning how these levels are calculated.

Exposures that will produce no observable reproductive effect at 1,000 times the level in question. For chemicals known to the State to cause reproductive toxicity, a warning is not required if the business causing the exposure 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” divided by 1,000. This number is known as the Maximum Allowable Dose Level (MADL). See OEHHA's website at: <http://www.oehha.ca.gov/prop65/getNSRLs.html> for a list of MADLs, and Section 25801 *et seq.* of the regulations for information concerning how these levels are calculated.

Exposures to Naturally Occurring Chemicals in Food. Certain exposures to chemicals that naturally occur in foods (i.e., that do not result from any known human activity, including activity by someone other than the person causing the exposure) are exempt from the warning requirements of the law. If the chemical is a contaminant² it must be reduced to the lowest level feasible. Regulations explaining this exemption can be found in Section 25501.

Discharges that do not result in a “significant amount” of the listed chemical entering 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 pass into or probably pass into a source of drinking water, 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” level for chemicals that cause cancer or that is 1,000 times below the “no observable effect” level for chemicals that cause reproductive toxicity, if an individual were exposed to that amount in drinking water.

² See Section 25501(a)(4).

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. 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. The notice must comply with the information and procedural requirements specified in Section 25903 of Title 27 and sections 3100-3103 of Title 11. A private party may not pursue an independent enforcement action under Proposition 65 if one of the governmental officials noted above initiates an enforcement 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 to stop committing the violation.

A private party may not file an enforcement action based on certain exposures if the alleged violator meets specific conditions. For the following types of exposures, the Act provides an opportunity for the business to correct the alleged violation:

- An exposure to alcoholic beverages that are consumed on the alleged violator's premises to the extent onsite consumption is permitted by law;
- An exposure to a Proposition 65 listed chemical in a food or beverage prepared and sold on the alleged violator's premises that is primarily intended for immediate consumption on- or off-premises. This only applies if the chemical was not intentionally added to the food, and was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination;
- An exposure to environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises;
- An exposure to listed chemicals in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking non-commercial vehicles.

If a private party alleges that a violation occurred based on one of the exposures described above, the private party must first provide the alleged violator a notice of special compliance procedure and proof of compliance form.

A copy of the notice of special compliance procedure and proof of compliance form is included in Appendix B and can be downloaded from OEHHA's website at:
<http://oehha.ca.gov/prop65/law/p65law72003.html>.

FOR FURTHER INFORMATION ABOUT THE LAW OR REGULATIONS...

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900 or via e-mail at
P65Public.Comments@oehha.ca.gov.

Revised: May 2017

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.7, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

CERTIFICATE OF MERIT

I, Kevin J. Cole, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged the party identified in the notice has violated California Health and 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 has reviewed facts, studies, or other data regarding the alleged exposure to the listed chemical that is the subject of the 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 Plaintiff's 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: March 1, 2020

Kevin J. Cole, Esq.
KJC Law Group, A Professional Corporation
Attorneys for Zachary Stein

CERTIFICATE OF SERVICE

I, Chen Wang, declare that I am over the age of 18 years, and am not a party to the within action. I am employed in the County of Los Angeles, California, where the mailing occurs; and my business address is 6700 Fallbrook Avenue, Suite 207, West Hills, CA 91307.

On March 2, 2020, I served the following documents: **(1) 60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH HEALTH & SAFETY CODE SECTION 25249.7(d); (2) CERTIFICATE OF MERIT; (3) PROPOSITION 65: A SUMMARY; and (4) CERTIFICATE OF MERIT ATTACHMENT (served only on the Attorney General)** on the party listed below by placing a true and correct copy thereof in a sealed envelope, addressed to each party and depositing it at my business address with the U.S. Postal Service for delivery by Certified Mail with the postage thereon fully prepaid:

Via Certified Mail

Black Diamond Supplements, LLC
c/o Brian Gamaly (Agent for Service of Process)
7120 E. Indian School Rd., Ste E.
Scottsdale, AZ 85255

On March 2, 2020, I served the California Attorney General (via website Portal) by uploading a true and correct copy thereof as a PDF file via the California Attorney General's website.

On March 2, 2020, I transmitted via electronic mail the above-listed documents to the electronic mail addresses of the City and/or District Attorneys who have specifically authorized email service and the authorization appears on the Attorney General's website.

See Attached Service List

On March 2, 2020, I served the following persons and/or entities at the last known address by placing a true and correct copy thereof in a sealed envelope and depositing it at my business address with the U.S. Postal Service for delivery with the postage thereon fully prepaid, and addressed as follows:

See Attached Service List

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

Executed on March 2, 2020 in Los Angeles, California



Chen Wang

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