

March 26, 2021

Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
1001 I Street, 23<sup>rd</sup> Floor  
Sacramento, CA 95812-4010

*Via portal at:* <https://oehha.ca.gov/comments>

**SUBJECT: COMMENTS TO PROPOSED AMENDMENTS TO ARTICLE 6, CLEAR AND REASONABLE WARNINGS SHORT-FORM WARNINGS**

Dear Ms. Vela:

We respectfully submit on behalf of the Dental Trade Alliance (“DTA”) the following comments to the Office of Environmental Health Hazard Assessment’s (“OEHHA”) *Notice of Proposed Rulemaking: Amendments to Article 6, Clear and Reasonable Warnings Short-Form Warnings* (“Proposed Rulemaking”), dated January 8, 2021. The DTA is a member supported trade association of suppliers and service providers to the oral health profession and industry, with the goal of improving the state of oral care. The organization provides resources, knowledge-sharing opportunities and advocacy that supports businesses throughout North America and with ties to the rest of the globe.

The DTA opposes the Proposed Rulemaking. First, our members currently using the short-form warning chose it in good faith as a legally compliant means of providing California consumers with the required warning, and of insulating themselves from the punitive lawsuits associated with the private enforcement of Proposition 65. DTA questions how changing the short-form warning after a brief period of usage improves overall compliance with Proposition 65. These companies invested time and capital redoing packaging and label artwork based on OEHHA’s 2018 amendment to Article 6 authorizing the short-form warning, expenses which they will incur again if forced to abandon the warning as currently written. Furthermore, the message to consumers will be diluted in the near term by a marketplace where multiple Proposition 65 consumer product warnings exist utilizing different language: 1) the existing long-form warning; 2) the “new” short-form warning; and 3) the “old” short form warning on those legacy products grandfathered under the proposed amendment.

Second, our members’ products are regulated by the U.S. Food and Drug Administration (“FDA”) as medical devices and must comply with the FDA’s labeling requirements. These requirements mandate that medical device product labels convey many data elements of information, and our members’ have designed their labels to comply with them and with the existing Proposition 65 short-form. This scenario will be complicated if the short-form warning is amended to require the identity of the listed substance, usually a long chemical name. Again, this will trigger the need to redesign labels and change packaging. Ultimately, the increased costs associated with these changes will be passed on to the purchaser, making our members’ medical devices more expensive to the users.

Third, restricting the use of the short-form warning to labels five square inches or less, while at the same time requiring the names of chemical substances, will eliminate it as a choice for products with other agency

labeling requirements, like medical devices. OEHHA has offered no support for its arbitrary five-inch size choice, nor has it explained how the current short-form fails to provide a prominent and conspicuous warning to consumers when the label exceeds five square inches. In fact, the proposed size restriction contradicts OEHHA's recent publication that Article 6 contains "no size limitation for which products could utilize short-form warnings." See, OEHHA's Proposition 65 Clear and Reasonable Warnings Questions and Answers for Business, A25 at p. 10 (Rev. May 2019), available at [Article 6 Questions and Answers for Business \(ca.gov\)](#).

Fourth, OEHHA's proposed action runs counter to the recent agency trend promoting the value of warning symbols rather than words. For example, medical device warnings incorporating recognized international symbols, even without adjacent explanatory text, have been recognized by the FDA as effective. See, <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling>. Likewise, the United Nations and the U.S. Department of Labor's Occupational Safety and Health Administration have modernized hazardous chemical warnings by adopting labeling practices that utilize warning pictograms and symbols as a primary means of communicating the presence of hazardous material. See, <http://unece.org/labels-ghs>; <https://www.osha.gov/hazcom>. This agency trend make sense, as symbols do not require translation, an important factor in our increasingly multicultural society.

OEHHA's proposed amendment does just the opposite. The current short form effectively communicates the presence of a listed substance by including the triangle/exclamation point symbol, the use of the word "warning," the identity of the end point and the contact email address. The Proposed Rulemaking dilutes the symbol's quick delivery of the relevant safety information by requiring additional and often confusing chemical names. In turn, instead of informing consumers at the point of purchase that a product's composition triggers the need for a Proposition 65 warning but is safe for use, the proposed new short-form label will confuse consumers as to the safety of the product by, in effect, scaring them with long, unpronounceable chemical names.

In sum, the DTA objects to the Proposed Rulemaking requiring the short-form warning to identify the specific chemical substances found in the products and limiting its use to labels five square inches and smaller. The public policy benefit of informing the consumer that a product contains a substance known to the State to cause "cancer," "birth defects," or "reproductive harm" is accomplished *via* those words. Adding a litany of technical chemical names unknown to most individuals does not improve that communication. It will simply increase the cost of compliance, with little to no public benefit.

Thank you for your consideration of our comments. Please feel free to contact either of the undersigned if you require any more information regarding this submission.

Sincerely,



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Greg Chavez  
Chief Executive Officer



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Rick Van Arnam  
Regulatory Affairs Counsel