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April 8, 2015

Ms. Monet Vela
Office of Environment Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Sent electronically to: P65Public.comments@oehha.ca.gov

SUBJECT: Clear and Reasonable Warning Regulations and Lead Agency Website Regulation

Dear Ms. Vela:

The Consumer Healthcare Products Association (CHPA) is the 134-year-old trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements (chpa.org). I am writing on behalf of CHPA members to address the most recent proposed reforms to the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) warning requirements proposed by the Office of Environment and Health and Hazard Assessment (OEHHA).[1] CHPA would first like to thank OEHHA for considering our comments submitted in response to the March 7, 2014 draft regulation and for providing an additional opportunity to respond to the latest (January 12, 2015) draft of the regulation.

Our comments below cover the proposed changes to Clear and Reasonable Warnings, the proposed development of a Lead Agency Website and OEHHA's conclusion that these proposals will have no impact on companies doing business in California. In addition to the comments provided herein, we have joined a coalition of organizations in endorsing comments from the California Chamber of Commerce on the proposed draft regulations which include a detailed analysis of the significant economic impact that these proposals will have on businesses operating in California.

As we noted in our June 2014 comments addressing the initial proposed revisions to the Warning regulations, CHPA agrees that reasonable reforms to Proposition 65 are needed and we commend OEHHA's attempts in this regard. However, we continue to believe that the focus of reform efforts should be on reducing or eliminating the ever increasing number of frivolous lawsuits plaguing the system, while continuing to protect human health and the environment. As such, we remain concerned that several aspects of these proposed changes continue to ignore our earlier expressed concerns regarding the highly likely effects of these proposals. In addition, we ask below that OEHHA provide specific examples of how these regulations will be enacted as

[1] A draft of the proposal was originally posted to OEHHA's website on March 7, 2014 at http://oehha.ca.gov/prop65/warnings/pdf/DraftWarningRegs030714.pdf. Subsequent proposed regulations were posted on January 12, 2015 pertaining to Clear and Reasonable Warnings and development of a Lead Agency Website.

well as provide the underlying evidence for their statements that the proposed warning requirements represent an improvement over what is currently required and that litigation will be reduced as a result of these efforts.

As proposed, the current draft regulations fail to address concerns for enhanced frivolous litigation, inconsistent and excessive warnings, and increased consumer confusion regarding certain provisions of the warning. We ask that OEHHA carefully take into consideration the comments we provide herein while keeping in mind the goals of the regulation including Governor Brown's goal of reducing unnecessary litigation. Several of the proposed changes would result in consumer confusion, increase label clutter, increase manufacturer costs and seem designed in order to enhance frivolous lawsuits against companies. For instance, the proposed requirements to name one (or more) of twelve chemicals as well as to not "dilute" or "diminish" the warning through the provision of supplemental information are likely to provide increased opportunities for the type of litigation which these reforms seek to end.

Article 6 Clear and Reasonable Warnings (Subarticle 1 – General)

§ 25600 General

Subdivision (b) notes that the proposed warning regulations will become effective two years after the date of adoption. While this represents an improvement from the originally proposed (September 2014) one year allowance, this still places an undue burden on manufacturers and does not consider marketplace conditions. It is not uncommon for products to remain in the marketplace for more than two years. We recommend that OEHHA either increase the amount of time for the regulation to become effective after the date of adoption or insert a provision that would grandfather in products containing a warning complying with the current law.

Subdivision (d) notes that supplemental information may be provided to individuals but that it "may not contradict, dilute, or diminish the warning". As noted in our June 2014 comments, we maintain that terms such as "dilute" or "diminish" are vague and subject to broad interpretations. For example, if the basis of a listing is mouse studies, does providing this factual information dilute or diminish the warning or does it provide important perspective to a consumer? Perhaps it would be helpful for OEHHA to provide clear guidance regarding information which would not be considered to dilute or diminish a warning. Lacking any clear guidance in this regard, private enforcers are likely to interpret any information as contradicting, diluting or diminishing a warning, and ultimately the court would have to resolve these questions. The end result will likely be increased frivolous lawsuits resulting in businesses submitting less correct and truthful information to consumers for fear of inviting litigation.

Article 6 Clear and Reasonable Warnings (Subarticle 2 – Safe Harbor Methods and Content)

§ 25602 Chemicals Included in the Text of a Warning

The current proposed regulation maintains the provision to specifically name any one (or more) of twelve chemicals, exposures to which OEHHA considers "commonplace". OEHHA has provided reasons for selecting these 12 chemicals including "potential for significant exposure"; "[r]ecent Proposition 65 enforcement activity"; "[r]ecognizability of the chemical name among the general public; and "general availability of additional authoritative information and resources

for the public on the toxicity and exposure to the chemical, doses of concern, and ways to prevent or reduce exposure". OEHHA has also noted that the chemicals required to be specifically named "may be changed over time as the public becomes familiar with the improved warning format".

CHPA has concerns with the underlying reasoning behind a number of these criteria, including using recent enforcement activity and public recognizability of chemical names as justification for naming any one of these chemicals and the lack of transparency in reaching these decisions. It is unclear how OEHHA decided that this is represents an "improved warning format"[2] or if they have evaluated the "recognizability of the chemical name among the general public". Since these decisions appear arbitrary, we ask that OEHHA disclose any and all information on consumer testing (or other material related to this provision) they may have. Further, without a rigorous evaluation of the extent of these changes on consumer understanding of chemical exposures (and possible ways in which to reduce or avoid exposure), it remains unclear how this provision represents an improvement over the currently required warning.

§ 25604 Warning Content

The proposed regulation specifies that to comply with the warning requirements a product requiring a warning would need to include a symbol consisting of a black exclamation point in a yellow triangle with a bold black outline. The symbol is similar to that used by ANSI[3] and OEHHA notes that this is used extensively by businesses in the United States and internationally. The extent to which this symbol will be readily recognized and understood by the general public is currently unclear and OEHHA has not provided any support for the proposed symbol being "presently more familiar to the general public". We ask that OEHHA conduct a consumer comprehension analysis to determine that the intended effect of enhanced understanding of potential chemical exposures and their resultant consequences occurs following placement of a Proposition 65 warning symbol on a product.

In the latest draft of the regulation, OEHHA has proposed to use the following "This product can expose you to a chemical [or chemicals] known to the state of California to cause cancer." While this represents an improvement over the formerly proposed "will expose" language, CHPA continues to believe that the current Proposition 65 language stating "This product *contains* [emphasis added] a chemical known to the state of California to cause cancer" is more recognizable to consumers and adequately conveys the necessary information. OEHHA maintains that citizens want to be informed about actual exposures and not "vague warnings about the content of the products". As noted above regarding the specific naming of one or more of twelve chemicals, OEHHA provides no solid evidence for this proposed change only their interpretation that the current warning language is insufficient.

[2] OEHHA January 16, 2015 Initial Statement of Reasons – Regulations for Clear and reasonable Warnings (page 22)
[3] American National Standards Institute

Article 2 Section 25205 Lead Agency Website

§ 25205 Lead Agency Website

Claiming that the public has no centralized source for obtaining supplemental information[4] regarding warnings, OEHHA has proposed to establish a framework for a website which they would manage providing information to the public concerning exposures to Proposition 65 chemicals. The proposed regulations would allow OEHHA to "collect existing, publicly available information and make it accessible" to those seeking additional information on Proposition 65 warnings. OEHHA could also request manufacturers, importers and distributors to provide supplemental information.

We appreciate the fact that OEHHA considered our earlier request and separated the proposed regulation of development of a Lead Agency Website from the Clear and Reasonable Warnings provision. However, as stated in our earlier comments, it remains unclear what type of information OEHHA seeks to collect from product manufacturers, how the OEHHA-maintained website will be developed and structured to ensure greater consumer awareness of exposures and potential means of avoiding exposures, as well as to what extent any included information will be reviewed prior to inclusion on the website. Further, OEHHA has not provided any detail on how it plans to provide information to the public regarding chemicals listed based exclusively on results from animal studies and/or chemical structure function relationships (*i.e.*, in the absence of human data).

We also remain concerned that several terms within the proposed regulation remain vague, including the provision of "reasonably available information concerning the anticipated level of human exposure to the listed chemical" on the website. Because OEHHA has not provided a detailed example of how the process may work, companies will have to continually monitor the website to ensure that no erroneous, false or misleading "reasonably available" information is incorporated onto the website.

CHPA remains concerned that OEHHA has not addressed the extent to which any information included on the website will be reviewed externally prior to inclusion on a public website. Despite providing consumers more information on a particular chemical, the beneficial consequences of such information remains unclear, especially given concerns associated with generally low levels of health literacy in the United States. As an example, the Food and Drug Administration has stated that drug labeling should be written "at a 4th to 5th grade reading level and no higher than an 8th grade reading level."[5] This represents another scenario where it would be helpful for OEHHA to provide an example of how the website for a particular chemical will be structured in order that stakeholders may provide more meaningful comments. Although OEHHA has provided a process to allow requests for a correction of material provided on the website it remains unclear what type of approach will be used to determine what information is ultimately included on the website.

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[4] Including information on how consumers may be exposed; how they may reduce or avoid exposure

[5] FDA, Guidance for Industry, Label Comprehension Studies for Nonprescription Drug Products (Aug. 2010)

Economic Impact Analysis

OEHHA believes that this proposed regulation will have no significant economic impact on businesses subject to the warning requirements of Proposition 65.[6] CHPA strongly disagrees with this assessment and asks that OEHHA review the detailed economic assessment report commissioned by the California Chamber of Commerce and provided in their comments to these regulatory proposals.

CHPA asks that OEHHA carefully review the concerns expressed in this letter and consider the possible negative effects that some of these proposed changes may have on companies doing business in California. We believe that the significance of the proposed changes requires additional disclosures from OEHHA regarding how these changes would improve the currently mandated warnings and enhance consumer understanding of exposures and ways in which to avoid them.

Thank you for the opportunity to provide these comments. Should you have any questions or require additional information please do not hesitate to contact me.

Respectfully submitted,

Jay Sirois, Ph.D.
Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

[6] OEHHA January 16, 2015 Initial Statement of Reasons – Regulations for Clear and reasonable Warnings (page 43)