Council for Responsible Nutrition
1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

April 26, 2016

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010
1001 I Street
Sacramento, CA 95814
Via Email: P65Public.Comments@oehha.ca.gov

RE: Notice of Modification to Proposed Regulation – Article 6, Clear and Reasonable Warnings

Dear Ms. Vela:

On behalf of the Council for Responsible Nutrition (CRN), thank you for the opportunity to provide comments to the California Office of Environmental Health Hazard Assessment (OEHHA) regarding its March 25, 2016 Notice of Modification to Proposed Regulation to repeal Article 6 and adopt a new Article 6 in Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act (Proposition 65). The Modified Proposed Regulation (Modified Proposal) amends OEHHA's Notice of Proposed Rulemaking published on November 27, 2015 (Initial Proposal).

CRN, founded in 1973 and based in Washington, DC, is the leading trade association representing the dietary supplement and functional food industry. Our membership includes more than 150 companies that manufacture nutritional ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies comply with a host of federal and state regulations governing the manufacturing, quality, and safety of dietary supplements and food, including those imposed by Proposition 65. CRN is also one of the over 200 California-based and national organizations and businesses in the Proposition 65 Coalition (the Coalition) led by the California Chamber of Commerce.

On January 25, 2016, CRN submitted comments to OEHHA outlining our concerns regarding its Initial Proposal. Those comments expressed concerns about the risk of increased litigation due to a lack of sufficient clarity and guidance for businesses. It also raised questions about the potential public health benefit that would result from the revised warnings and the scientific basis for these changes. And because dietary supplement and food labeling are already heavily regulated at the federal level, the proposal would impose unnecessary label changes that are likely to alarm and confuse consumers. CRN also joined the Coalition comment letter, which raised several issues of mutual concern to the business community and highlighted several areas of the Initial Proposal in need of revision.

While the Modified Proposal attempts to address some of these issues, OEHHA continues to ignore the legitimate and significant concerns raised by CRN and the Coalition. From a practical, legal, and scientific standpoint, the Modified Proposal (like its previous iterations) is fundamentally flawed. CRN's outstanding concerns are summarized below, and we incorporate by reference the comments submitted on behalf of the Coalition.

Finally, given that OEHHA has failed to sufficiently address the numerous concerns of the dietary supplement industry and other industries, CRN also requests that OEHHA revise the Modified Proposal and allow for an additional public comment period.

Section 25600: General

OEHHA should extend the two-year effective date in subsection (b) to three years and add the term "or packaged." Based on our members' knowledge and experience with dietary supplement packaging and labeling matters, two years will not provide businesses with adequate time to comply with the new warning requirements. Some dietary supplements, such as vitamin or mineral tablets, have a long shelf-life and may remain in the stream of commerce longer than two years. For example, iron mineral supplements are relatively stable and have longer expiration dates, or no expiration dating at all. In addition, or in the alternative if OEHHA intends to maintain the two-year effective date, we recommend that OEHHA clarify that this subsection applies to consumer products manufactured or packaged prior to the effective date, as follows:

> (b)…A warning for a consumer product manufactured or packaged prior to the effective date of this article is deemed to be clear and reasonable if it complies with the September 2008 revision of this article.

Without this change, businesses will be forced to recall and re-label otherwise compliant products, incurring unnecessary costs and burdens that will also impact retailers. CRN also requests that OEHHA provide specific guidance in its Final Statement of Reason (FSOR) to address the grandfathering of dietary supplement product labeling to assure effective implementation of the proposed regulation and avoid unnecessary compliance costs on the industry.

Section 25600.1: Definitions

OEHHA should remove the phrase "any reasonably foreseeable use" and further refine the definition of "consumer product exposure." Subdivision (e) defines "consumer product exposure" as "an exposure that results from a person's acquisition, purchase, storage, consumption, or any reasonably foreseeable use of a product, including consumption of a food." The phrase "any reasonably foreseeable use" is vague, overly broad, and a target for litigation by private enforcers. By not defining "consumer product exposure" according to the use of a particular product, such as a dietary supplement that has specific directions for use or customary (ordinary) uses, the definition may be interpreted to require manufacturers to assess all potential types of exposures to a listed chemical beyond oral use of the product. Instead, the definition should be narrowed to apply only to those exposures that are consistent with the product's directions for use or the ordinary conditions of use, which reflects FDA's safety provisions related to the use of dietary supplements.[1] CRN suggests the following changes:

> (e) Consumer product exposure means an exposure that results from a person's acquisition, purchase, storage, consumption, ~~or any reasonably foreseeable use of a product,~~ including consumption of a food, in accordance with the product labeling recommendations or ordinary conditions of use.

[1] Under 21 USC § 342(f), a dietary supplement is considered adulterated if it "presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."

Section 25601: Safe Harbor Clear and Reasonable Warnings – Methods and Content

OEHHA should maintain the existing description of "clear and reasonable warning" and provide guidance for businesses seeking to use a fully compliant alternative warning. Proposed subsection (b) suggests that businesses are permitted to use alternative warning content or methods other than those provided in the regulations. However, the proposal fails to provide a definition or guidance as to what is considered a "clear and reasonable warning." As a result, the only way to mitigate the threat of litigation is for businesses to use the new safe harbor language. If OEHAA truly intends to provide businesses with the ability to use alternative warnings, then the definition of "clear and reasonable warning" must be restored and included in the final regulation, along with guidance to assist businesses in providing a fully compliant warning.

OEHHA should revise subsection (c) and clarify the chemical specification requirement. CRN agrees with the Coalition's comments that the chemical specification requirement has significant legal implications for businesses, including the dietary supplement industry. Proposed subsection (c) states that a warning is compliant if "the name of one or more of the listed chemicals for which the person has determined a warning is required is included in the text of the warning." Although OEHHA has removed the phrase "to the extent that an exposure to that chemical or chemicals is at a level that requires a warning," the modified language imposes the same unlawful burden on businesses by requiring proof that a warning is required.

As stated in our previous comments, Proposition 65 only requires defendants to prove that no warning is required; it has never been interpreted to require defendants to justify a decision to warn. In doing this, OEHHA also creates a new source of litigation for private enforcers to challenge the existence of a warning, in addition to its content due to the proposed chemical specification requirement. If OEHHA is intending to reduce "overwarning" we once again suggest it focus on improving the scientific basis for Proposition 65 overall, rather than adding an additional burden on defendants. OEHHA should remove the phrase "for which the person has determined a warning is required" and replace it with the phrase "for which a warning is being provided" as follows:

> Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals for which a warning is being provided ~~the person has determined a warning is required~~ is included in the text of the warning.

As noted by the Coalition, this language is also consistent with other agency regulations, including OEHHA's recently finalized (Bisphenol A) BPA emergency regulation and OEHHA's Lead Agency Website regulation.

In addition, subsection (c) continues to lack sufficient clarity regarding how a business should select the "one or more of the listed chemicals" to be included in the warning, creating yet another source of litigation. Some CRN members market dietary supplement products with multiple ingredients, many of which are from natural sources (e.g., herbal ingredients) and have multiple chemical constituents that in the future may become subject to the Proposition 65 warning requirements. If OEHHA intends to allow companies to select one chemical to include in the warning, even if the warning is being provided for multiple chemicals, OEHHA must state this explicitly in the regulation and/or the FSOR. Otherwise, a private enforcer could easily challenge a business's decision to include only one chemical in the

Proposition 65 warning. CRN recommends that OEHHA consider the following additional language suggested by the Coalition to avoid unnecessary litigation in this area:

> If a warning is being provided for more than one listed chemical, the warning meets the requirements of this article if the name of at least one of the listed chemicals for which the warning is being provided is included in the text of the warning.

CRN also suggests that OEHHA consider providing detailed guidance as to the criteria for selecting one or more chemicals. These selection criteria should be based on sound scientific reasoning and provided to the public for comment.

OEHHA should eliminate or modify subsection (f) to remove the broad, unconstitutional restriction on supplemental information. CRN agrees with the Coalition's comments regarding First Amendment and due process concerns. Although the Modified Proposal removes language stating that information supplemental to a warning "may not contradict the warning," the revised language under proposed subsection (f) now states that supplemental information is permitted "only to the extent that it explains the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals." This revised language raises the same issue: it suppresses constitutionally protected free speech by imposing a vague, overly broad restriction on supplemental information. Thus, CRN recommends that OEHHA eliminate this subsection in its entirety. Alternatively, we suggest that OEHHA adopt the modifications put forth by the Coalition in its comment letter to narrow the scope of the restriction on supplemental information.

Section 25607: Specific Product, Chemical and Area Exposure Warnings

OEHHA should revise or eliminate subsection (b) to prevent confusion and remove an unlawful burden on businesses. This subsection states that "if a person does not cause an exposure to a listed chemical required to be identified in a warning set out in this section, the name of that listed chemical need not be included in the warning" in order to comply with Subarticle 2. However, it further states that "the name of at least one chemical requiring a warning must be included in all warnings." As written, this subsection is confusing and seems to suggest, similar to the language in proposed subsection 25601(c), that businesses have the burden of proving that a warning is in fact required. CRN requests that OEHHA eliminate this subsection, which is unnecessary and fails to provide any clarity with regard to compliance. Alternatively, we request that OEHHA modify the language in accordance with the recommendations outlined in our comments to subsection 25601(c) to avoid the implication that businesses are required to prove that warning is in fact required.

Section 25607.1: Food Exposure Warnings – Methods of Transmission

OEHHA should specify that only one method of transmission is required. Proposed subsection (a) states that a warning for food exposures, including dietary supplements, is compliant if it meets the applicable content requirements and "is provided using one or more of the following methods." This language is likely to be misinterpreted by private enforcers who will claim that multiple warning methods are required or challenge the adequacy of a chosen warning method. To avoid litigation in this area, CRN recommends that OEHHA modify the language to state that a warning complies if it meets the content requirements and "is provided using at least one of the following methods." Second, either in the final

regulation or the FSOR, OEHHA should explicitly state that businesses have sole discretion when determining which warning method to use.

CRN also appreciates that OEHHA has removed the type size and font size requirements in subsection (a) and other areas of the proposed regulation. However, OEHHA instead proposes subsection 25601(d), which appears to apply to food exposure warnings, and states that "Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use." This language is ambiguous and private enforcers are likely to challenge the "conspicuousness" of the warning and whether it is "likely to be read and understood by an ordinary individual under customary conditions of purchase or use." Thus, CRN recommends OEHHA simplify the language as follows:

> (d) Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign~~, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices~~ on the label, labeling, or sign~~, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use~~.

OEHHA should revise subsection (b) to include the term "labeling" and remove the set off, boxed warning requirement. OEHHA defines the term "labeling" to include materials (written or otherwise) that accompany a product and the term is used throughout the Modified Proposal. However, it is unclear whether a warning transmitted through "labeling" is compliant, as currently permitted under the existing regulations. CRN recommends that OEHHA revise subsection (b) to include the term "other labeling" so that the regulations continue to allow for warnings in package inserts and related methods that may contain other health and safety information or warnings for consumers.

Proposed subsection (b) also requires that for food exposures, including dietary supplements, on-product warnings must be "set off from other surrounding information" and "enclosed in a box." This requirement is unnecessary and likely to cause alarm and confusion among consumers. The federal Food and Drug Administration (FDA) reserves boxed warnings, also referred to as "black box" warnings, for medications with a significant risk of serious or life-threatening adverse effects or drugs approved by FDA on the condition that distribution or use is restricted.[2] For example, FDA recently announced that immediate-release opioid pain medications will now require a new boxed warning about the serious risks of misuse, abuse, addiction, overdose and death.[3] The FDA has never required a boxed warning for a dietary supplement and is not warranted for Proposition 65 warnings.

In addition, the dietary supplement and food industry is subject to numerous product labeling requirements under federal law that address the size and placement of information that must be provided on the label.[4] Many dietary supplement products are sold in small packages, for which little if any label space is available

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[2] See FDA, Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format, Guidance for Industry (October 2011), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075096.pdf.

[3] FDA News Release: FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death (March 2016), available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[4] 21 CFR § 101 et seq., Food Labeling.

for including a boxed warning. Using larger containers in order to accommodate larger product labels adds to environmental waste and imposes additional, unnecessary costs on businesses. Further, the warning itself, without an enclosed box, adequately conveys the necessary information to consumers.

OEHHA should reconsider its foreign language requirement for food exposures. Although OEHHA has revised the definition of "consumer information" and removed the reference to "label, labeling or sign, for purposes of triggering the foreign language requirement, the term "consumer information" remains overly broad. In addition, CRN again questions whether OEHHA has carefully reviewed how this requirement impacts the relevant federal labeling mandates for dietary supplements and food. As noted above, the federal labeling regulations and the small packaging of many dietary supplement and food products restrict the amount of available space for additional label warnings or other product information in other languages. Further, these regulations already address foreign language requirements for product labeling.[5] For example, if any foreign language is used on the label, all other product information must be translated into that language. As a result, a dietary supplement label with three languages (e.g., English, French, and Spanish), must also provide the Proposition 65 warning statement in three languages. Even if OEHHA were to give businesses flexibility, dietary supplement companies must follow the federal labeling laws without exception and place all legally-required information on the label in the format provided therein. Therefore, CRN renews its request to OEHHA to eliminate the foreign language requirement for food exposures until OEHHA has conducted a thorough review of relevant federal labeling requirements for dietary supplement and food products, expressly identifies potential conflicts, and explains to stakeholders how its proposed regulations should be reconciled with the federal requirements.

Section 25607.2: Food Exposure Warnings – Content

OEHHA should restore the original safe harbor language for food exposures to reflect the nature of dietary supplement and food products and avoid consumer confusion. CRN's comments to the Initial Proposal outlined in detail why the proposed language for food exposures is not appropriate and its potential impact on consumers' understanding of the safety and quality of dietary supplement and food products. Thus, we urge OEHHA to carefully review CRN's January 2016 comments, which are summarized below.

The current safe harbor language "may contain" reflects the variability of the presence and levels of certain chemicals that are naturally found in food products. This term also allows flexibility and more accurately describes the potential exposure of dietary chemicals in dietary supplement and food products. The phrase "consuming this product can expose you to…" is unnecessarily alarming and inconsistent with the federal regulation of dietary supplements and food, which includes detailed labeling provisions and requirements for assessing contaminant levels, among other things. Similarly, the proposed language is also likely to confuse consumers by elevating the level of risk of consuming these products, as they may erroneously conclude that the product presents an undue risk of cancer or reproductive harm. The comprehensive regulatory framework for dietary supplements addresses all aspects of safety including good manufacturing practices (GMPs), ingredient and product safety, along with detailed requirements to ensure consumers receive accurate and informative labeling. Food products are also subject to similar laws and regulations governing GMPs, safety, and labeling. In summary, OEHHA's proposed language presents a conflicting

[5] See 21 CFR § 101.15(c)(2) regarding the use of label space for any representation in a foreign language; see also 21 CFR § 101 et seq., Food Labeling.

message about product safety that consumers may misinterpret and is unnecessary given that the current safe harbor language appropriately conveys the required information to consumers.

Thank you for considering our comments and providing the opportunity to participate in the regulatory process. Should you have questions, please do not hesitate to contact me at ral-mondhiry@crnusa.org or (202) 204-7672.

Sincerely,

Rend Al-Mondhiry
Associate General Counsel