Natural Products ASSOCIATION™
Promoting Natural Products for Healthy Lifestyles

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

Sent Electronically to: P65PublicComments@oehha.ca.gov

Subject: "RE: Proposed Repeal of Article 6 and Adoption of New Article 6 –Clear and Reasonable Warnings"

Dear Ms. Vela:

On behalf of the Natural Products Association (NPA), thank you for the opportunity to submit comments to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) regarding the notice of proposed rulemaking to repeal Article 6 and adopt a new Article 6. NPA is submitting this letter as general comments to OEHHA's new Article 6, Clear and Reasonable Warnings.

NPA is the trade association representing the entire natural products industry. We advocate for our members who supply, manufacture, and sell natural ingredients or products for consumers. NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. NPA has set numerous industry standards, such as dietary supplement Good Manufacturing Practices (GMPs), as well as a definition of natural for home care and personal care products. NPA is the

oldest and largest trade association in the natural products industry, representing nearly 2,000 members and accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids, has led the charge to keep the natural products industry in business for over 78 years. The NPA is a non-profit 501(c)(6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. Of particular concern to NPA members is the new Article 6 on "Clear and Reasonable Warnings" because most NPA member companies do business in California and are therefore impacted by these changes. Thank you for the opportunity to comment.

NPA supports Governor Brown's May 7, 2013 press release promising reforms to "revamp Proposition 65 (Prop 65) by ending frivolous 'shake-down' lawsuits, improving how the public is warned about dangerous chemicals and strengthening the scientific basis for warning levels."[1] Following the Governor's announcement, OEHHA held a public meeting and developed a pre-regulatory draft amending Article 6 Clear and Reasonable Warnings. In OEHHA's Initial Statement of Intent, the Agency states that its proposed changes to Prop 65 Article 6 Clear and Reasonable Warnings are to address the Administration's vision and would "reduce unnecessary litigation and require more useful information to the public on what they are being exposed to and how they can protect themselves,"[2] and would provide certainty for businesses subject to the Act. Based on our review of the pre-regulatory draft and the OEHHA presentation and comments expressed during the April 14, 2014 workshop, NPA submitted

[1] Press Release, Office of Governor Edmund G. Brown, Jr., Governor Brown Proposes to Reform Proposition 65. (May 7, 2013), available at http://gov.ca.gov/news.php?id=18026.
[2] OEHHA Draft Initial Statement of Reasons, p.4, March 7, 2014, available at http://oehha.ca.gov/prop65/warnings/pdf/ISORWarningreg030714.pdf

comments on April 8, 2015 regarding the new Article 6 Clear and Reasonable Warnings. On November 27, 2015, OEHHA announced its decision not to proceed with its original Notice of Proposed Rulemaking to Article 6 in Title 27 of the California Code of Regulations, dated January 19, 2015. Instead, the current proposal repeals and replaces the January 19, 2015 proposal initiating new rulemaking for public comment under the California Administrative Procedure Act.

NPA applauds the efforts of Governor Brown to reduce the incidence of frivolous lawsuits in the State of California under the private enforcement provisions of Proposition 65. NPA applauds OEHHA's efforts to address ambiguities and concerns raised by our previous comments on "Clear and Reasonable Warnings" dated April 8, 2015; however, NPA has significant concerns regarding the proposed adopted language for a new Article 6 "Clear and Reasonable Warnings". NPA believes that the changes in the present proposal, if adopted, do little to achieve the outcome outlined by Governor Brown and do not address safety for California consumers. The language in the proposal contains many ambiguities, force companies to interpret the Act's provisions, and subsequently leave companies vulnerable to litigation.

Proposed Chemical Specification Requirements Outlined in Section 25601(c) are Ambiguous and Subject to Interpretation

In its January 2015 Proposal, OEHHA required warnings to provide the name of one or more of 12 chemicals or chemical categories identified by OEHHA in the regulation. However, the new proposed Article 6 by OEHHA eliminates this requirement. OEHHA requires warnings to provide the name of one or more chemicals for which the warning is being provided (see below).

> *[A] warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided is included in the text of the warning, to the extent that an exposure to that chemical or chemicals is at a levels that requires a warning.*

It is unclear from the proposed new Article 6 language above how companies must comply. More specifically, it is not clear if a company has to list one, more than one, or all chemicals that are over the limit in a warning statement. If left unchanged, NPA interprets the language as suggesting that a warning must specify all of the chemicals for which a warning is being provided if the business determines to warning for exposures to multiple listed chemicals. It is our understanding that OEHHA's original intent in adopting a new Article 6 was to allow businesses to specify only one chemical in the warning, even if the warning is being provided for more than one chemical. The proposed requirement to identify "one or more of the listed chemicals" leaves companies open to litigation by bounty hunter plaintiffs who have never purchased the product for consumption. OEHHA's language does not serve the interest of California consumers but rather invigorate the plaintiff's bar.

NPA believes OEHHA needs to rework the proposed chemical specification requirement to be in line with its intent to identify one chemical. In its current drafted form, OEHHA's proposal fails to provide instruction to firms in the event of a warning for two chemicals. It is not clear which one of the two chemicals a firm should select and identify in its warning statement for consumers. One chemical could be more predominant in the product but the other chemical could pose a greater exposure threat to consumers. If it is the intent of OEHHA to leave such discretion to a business as to which relevant listed chemical it should identify in a warning, then it should be clearly stated. Without a clear chemical specification requirement, given the

ambiguities present in the proposed draft, firms will be subject to targeted enforcement by bounty hunter plaintiff's attorneys.

The ambiguity in the chemical specification requirement does not address the scenario when the product contains one chemical which is a reproductive toxicant and another which is a listed carcinogen. If the firm must identify only one (the proposed regulations call for selecting at least one) chemical in their warning statement, the warning statement may be false and misleading to the consumer. For example, a product may contain both a carcinogen and a reproductive toxicant and therefore its warning statement must include both categories. However, the ambiguous language in the proposed Article 6 re-draft requires them to list only one chemical. The company might list only the reproductive toxicant by name, but warn consumers that the product contains ingredients that may cause birth defects or other reproductive harm as well as warn consumers as containing a listed carcinogen known to the state. Since the carcinogen was not identified by name, the rest of the warning statement about carcinogens may have the unintended consequence of suggesting that the identified reproductive toxicant is also a chemical known to the State of California as causing cancer (a carcinogen), which would be false and misleading to a consumer. This proposed language for a new Article 6 would set firms up for future litigation. This was not the intent of voters of the Act.

The Proposed New Article 6 Shifts the Burden to Business to Demonstrate That a Warning is Required

The basis for any prop 65 litigation is the requirement that warnings specify a chemical "*to the extent that an exposure to that chemical or chemicals is at a level that requires a warning*." NPA recommends this language be removed in its entirety. This is an unlawful burden

for firms doing business in California, and it contradicts the provisions under the Safe Drinking Water and Toxic Enforcement Act of 1986 (the Act). In accordance with the Act, a warning requirement does not apply if:

> "*[a]n exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity*."[3]

Given this language in the Act, **the statutory burden on the defendant is to demonstrate that *no warning* is required**. On the other hand, the proposed language in § 25601(c) places the converse on firms doing business in California as it requires them to demonstrate that a warning is required. This language will serve as the basis of future litigation, and NPA strongly recommends its removal to remain in line with the intent of voters of the Act and Governor Brown's recent address to reform Prop 65.

For example, NPA does not see how the proposed changes would extend to warnings in court approved settlements, for those companies that are named in the court approved settlements, but would apply to other companies selling the same products. This will have the opposite effect intended by the governor, since this will essentially place all other persons and companies engaged in sales of products in the State of California at risk for litigation, even though they have carefully amended their product warnings to conform to the warnings provisions in the court approved settlements involving the same or similar products.

[3] Title 27 California Code, § 25249.10, Health and Safety Code.

The Proposed Article 6 Should Clarify Define "Labeling" in Accordance with the Federal Food Drug and Cosmetic Act and When to Use for Communicating Warnings

It is currently unknown whether warning statements must be communicated only in labels. However, there are other methods to communicate clear and reasonable warning statements to consumers such as package inserts, flyers, brochures, pamphlets, etc. in order to satisfy a firm's warning obligation under the Act. In fact, the plaintiff's bar will undoubtedly claim that transmitting warning statements in these types of advertisements and labeling is not permitted. Only OEHHA can clarify this issue with its proposed re-draft of Article 6.

The term "label" is defined in the proposal as "affixed to a product or its immediate container or wrapper", and "labeling" is defined as "any written, printed, graphic, or electronically provided communication that accompanies a product including tags at the point of sale or display of a product." The problem is that the section on methods of transmitting a warning in the proposed regulations *only* includes the following:

> "An on-product label that complies with the content requirements in Section 25603(b)."

The term "labeling" is nowhere to be found in this proposed subparagraph and is not consistent with the language in the current regulations. Under the current regulations, "label" and "labeling" denote the same thing with the exception that "labeling" includes communication accompanying a product. The current regulation states that a warning may be provided "on a product's label or other labeling." NPA recommends two changes here. NPA recommends the inclusion of "labeling" as the current regulations do. Second, NPA recommends the use of FDA's definitions for "label" and labeling in sections 201(k) and 201 (m), [U.S.C. 301(k) and 301(m)] respectively, of the Federal Food Drug and Cosmetic Act:

- Label to be defined as a "*display of written, printed, or graphic matter upon the immediate container of any article…*"
- Labeling[4] to be defined as "*all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying*[5] *such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce*."

NPA supports the use of communicating and transmitting warning statements to consumers through labeling as this is the place where a consumer will often seek for additional information regarding conditions of use for the product. Unfortunately, NPA believes that private enforcement litigators will interpret the proposed regulations to mean firms will never be allowed to transmit warning statements in pamphlets, brochures, and package inserts, which accompany the product. The terms "label" and "labeling" should be defined and clearly laid out in the proposed draft with clear examples of when transmitting warning statements in advertisements would be permitted and any instances in which it would not be allowed. The proposed regulations do not address whether the warning statement should be included on both the immediate container and outer packaging of the product. One could interpret the regulations to mean that placing a warning statement on the immediate container would suffice; however, many products contain an immediate container, which is placed into outer packaging. The proposed Article 6 regulations are far too ambiguous to provide clarity to questions which most firms will have from implementing these new measures in the Act if adopted. While the current

[4] According to an appellate court decision: "Most, if not all advertising, is labeling. The term 'labeling' is defined in the Federal Food Drug and Cosmetic Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."
[5] The term 'accompanying' is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. 'Accompanying' also includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

regulations suggest that pamphlets, public advertisements and other labeling may be appropriate avenues of warning methods,[6] NPA recommends that the proposed Section 25602 should be revised to continue to reflect these allowable alternatives. The proposed regulations may be interpreted to mean that pamphlets, advertisements and other systems of communications warnings, other than on labels, are not appropriate warning mechanisms.

Foreign Language Requirement in Section 25602(d) Should be Clarified

Section 25602(d) provides a foreign language requirement to warn consumers in both English and in whatever language where a foreign word appears on either the label or labeling. More specifically, 25602(d) provides the following:

> if any "label, labeling or sign that provides consumer information about a product is provided in a language or languages other than or in addition to English, then a warning for that product meets the requirement of this article only if the warning is also provided in the same language or languages on that label, labeling or sign."

NPA recommends that OEHHA adopt the federal statute in the Federal Food Drug and Cosmetic Act concerning its foreign language requirement to provide clarity and guidance to businesses on how to comply with this requirement. Title 21 of the Codified Federal Regulations section 101.15(c) suffers from the same ambiguity in terms of how the foreign language requirement regulation is enforced. It has caused FDA to be very inconsistent in how it has applied the regulation in warning letters to firms. For example, what if a foreign word is part of the name of the product? What happens if a foreign word is part of the established lexicon of the English

[6] Title 27 CCR § 255603.1(d).

language? Many English words have their roots in foreign languages after all. OEHHA's proposal states that the foreign language requirement is triggered only if 'consumer information' about a product is provided in that foreign language; however, 'consumer information' can be broadly interpreted and could encompass product names or words understood and contained in an English dictionary. If it is the intent of OEHHA to limit the foreign language requirement to specific circumstances, it should provide examples in its proposal as to when the foreign language requirement is triggered and when it is not.

OEHHA's New Article 6 Proposal is Overly Burdensome to Internet Retailers

Section 25602(b) requires warning statements to be given prior to an internet purchase, even if the product already contains the proper warning labels included by the manufacturer. These "prior to purchase" requirements impose a significant compliance burden to internet retail stores. It also appears to be in direct contradiction to section 25600.2(b), which attempts to minimize the burden to retail sellers. Under 25600.2(b), a retailer has no stated responsibility to warn if the manufacturer has already placed warning statements on products. Only in the setting where a retailer has covered, obscured or altered a warning label would the retailer have a compliance obligation. OEHHA's proposal has flipped the burden on internet retailers to affirmatively provide warning statements, whether or not a warning has been provided on the product label by the manufacturer. Therefore, the proposed regulations are in direct contravention to the current provisions and sections in the Act. Internet retailers will be targeted with pre-litigation letters because on-product labeling will be insufficient to protect these retailers. The economic and compliance burden of checking each product to make sure the internet retail website displays the proper warning statement will undoubtedly lead to

overwarning and desensitization of these warning statements by the California consumer. These new compliance burdens on internet retailers could also apparently be at odds with the interstate commerce clause. NPA strongly urges OEHHA to create an exemption for out-of-state internet retailers in their "prior to purchase" requirements.

NPA does not support OEHHA's new Article 6 on Clear and Reasonable Warnings

While the new Article 6 attempts to provide greater clarity, we believe it will not achieve the goals outlined by the Governor, and in some cases, it is contrary to OEHHA's previous expressed intent and contrary to other parts of the Act. NPA believes this new Article 6 will be counterproductive and have the opposite intended effect, leading to more "overwarning".

NPA believes the proposed new Article 6 will result in tremendous financial and resource challenges to businesses and will have the potential to create more compliance pitfalls resulting in a glut of new threatened or actual litigation. Consequently, the proposal will yield more rather than less frivolous lawsuits based on noncompliance issues unrelated to the quality of an exposure warning. It is arbitrary to move forward with these changes without actual empirical data to support any perceived benefits to consumers and without an assessment of the risk and legal vulnerability for businesses created by these warning changes.

OEHHA asserts there will be a reduction in frivolous lawsuits related to Prop 65 lawsuits for inadequate, unclear, and inconsistent warnings. As we commented earlier, NPA questions how many recent lawsuits, frivolous or otherwise, are based on inadequate or inconsistent warnings. A review of recent Prop 65 lawsuits and settlements indicate that the current genesis for the vast majority of threatened or actual lawsuits is not over the content of the warning, but

whether an exposure warning is even required at all. We believe imposing additional prescriptive requirements for Prop 65 warnings, requiring warnings by internet retailers, and requiring the submission of additional information to the OEHHA without addressing the core cause of most litigation is likely to trigger more frivolous lawsuits based on minor non-compliance issues unrelated to providing an adequate "clear and reasonable" warning of exposure to consumers. Under the provisions, companies can meet their regulatory responsibilities by determining if their product contains a listed chemical and then providing a "clear and reasonable" warning using either safe harbor language or more specific warning language when appropriate. NPA urges OEHHA to reconsider and abandon its latest draft proposal and others, similar to its decision to drop its last Article 6 proposal, until the Agency conducts a more thorough assessment of its impact on businesses.

Economic Impact

NPA appreciates OEHHA's goal of using technology to provide additional information regarding Prop 65 warnings, yet we caution the Agency to be realistic about its resources and capacity for implementing these changes and ongoing costs and challenges related to keeping the website maintained, updated and data protected. OEHHA does not present an economic impact analysis for the cost to the Agency, a cost that will be passed ultimately to the California taxpayers that support the Agency. Furthermore, OEHHA has not presented an economic impact analysis concerning costs to businesses, which will be considerable due to the heavy burdens that will result from new exposure warning labels for all foods and other consumer products.

In spite of having an economy that has ranked in the top ten worldwide since the 1970's, California is often found at the bottom of lists highlighting states which support business.

California ranked dead last in the Chief Executive's list of best and worst states for business published on May 24, 2014.[7] CEO comments about doing business in California tell a grim story: "California goes out of its way to be anti-business and particularly where one might put manufacturing and/or distribution operations." Or, "California could hardly do more to discourage business if that was the goal. The regulatory, tax and political environment are crushing." These comments support NPA's apprehensions about further regulatory changes to Prop 65 and the belief that California will continue to see a decline in its economy due to an increase in ubiquitous Prop 65 warnings and related shake-down lawsuits that become a barrier to attracting new businesses to the state and force companies to flee to more business-friendly states.

Conclusions

In summary, NPA has outlined its overarching concerns with the OEHHA's new Article 6. These comments support our contention that the proposed new Article 6 will not result in the reforms outlined by the Governor or OEHHA's stated goals, which are to reduce frivolous lawsuits and improve the quality of exposure warnings. NPA believes the old Article 6 Clear and Reasonable Warnings were adequate and appropriately allow business to prove that the Prop 65 warnings they issue are "clear and reasonable" by any means they wish. They set forth criteria to establish when warnings will automatically be deemed "clear and reasonable" for purposes of Prop 65. The current regulations also include "labeling" as avenues to transmit warning statements to consumers. The proposed regulations should define what "labeling" constitutes as

[7] http://chiefexecutive.net/California-is-the-worst-state-for-business-2014#sthash.pGzMUkXX.qvmN6VFk.dpuf

well as clarify the current regulations by providing examples where labeling could be used to transmit warning statements.

NPA also requests this proposal not be adopted in order to eliminate its anticipated burden on internet retailers. OEHHA's "prior to purchase" requirement will not protect internet retailers who rely on warning statements already contained on products by the manufacturer. This requirement would increase the burden on retail sellers and contradicts section 25600.2(b), which is designed to minimize that burden.

The draft proposal to revamp Article 6 is unclear regarding its foreign language requirement. It does not provide clarity to firms as to when a foreign word would trigger the foreign language requirement. For these reasons, NPA requests OEHHA abandon its Article 6 draft proposal on "Clear and Reasonable Warnings".

Thank you for your attention to these important matters and the opportunity to comment. Should you have any questions, please contact me directly at (202) 223-0101 Ext.101 or via email at Daniel.Fabricant@NPAinfo.org.

Best regards,

Daniel Fabricant, Ph.D.

CEO & Executive Director, NPA