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

Sent Electronically to: P65Public.Comments@oehha.ca.gov
Subject: "Potential Regulations Workshop"

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 potential regulatory actions. NPA would like to offer comments regarding possible regulatory actions to "Update the Naturally Occurring regulation (25501)."

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 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, which represents nearly 2,000 members 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 78 years. Of particular concern to NPA members are the possible regulatory actions to "Update the Naturally Occurring regulation (25501)."

NPA has traditionally supported the exclusion of chemicals that have been shown to occur naturally in foods from warning labeling requirements and would like to reiterate strong support of the retention of this exemption. NPA supports this exemption for naturally occurring chemicals in food, as well as the exemption of the use of those chemicals in non-food products. NPA agrees that removal of this exemption would "diminish the overall significance of food warnings" (22 C.C.R. Division 2, Part 2, Chapter 3, §12501). Additionally, any changes to this rule would impose an additional financial burden on our members, many of whom are small businesses already struggling to meet the rigorous labeling and regulatory demands of current California state laws.

NPA would however like to recommend clarifications to certain aspects of these exclusions, specifically the definition of the term "food." The federal definition of "the term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article" (21 U.S.C. §321(f).) Included under the umbrella of this definition are dietary supplements and medical foods. California has not adopted the federal definition of the term "food" which has been the root of more than a dozen lawsuits regarding dietary supplement labeling issues under Proposition 65. In a 2013 case (Stephen Gillett vs. Garden of Life, Inc.) in which the plaintiff charged the defendants with marketing and selling herbal supplements containing lead, without proper warning labels, the defendants argued that any exposure to lead through their products should be exempt from labeling requirements under the naturally occurring exemption for food. Inevitably this

argument called into question whether or not the products fell under the definition of “food”. The Honorable John E. Munter ruled that it was the intent of the California Health and Welfare Agency to adopt the federal definition of “food” for Proposition 65 under California's Sherman Food Drug and Cosmetic Law. Therefore, dietary supplements would be held to the same warning labeling standards under Proposition 65. To undermine future attempts at litigation in these matters, NPA strongly urges the adoption of the federal definition, to remove unnecessary ambiguity regarding dietary supplements and medical foods under current California state law.

Prop 65 could be considered the most stringent standard on the planet as it requires warnings for chemicals even if present at levels well below federal total tolerable intake levels, established with scientific evidence to achieve a public health outcome. The U.S. FDA, EPA, Institute of Medicine, and World Health Organization, have extensive research on the health impact and toxicity of common chemicals and set reasonable guidelines for total tolerable intake and exposure levels. Violation of federal levels set for contaminants can result in a warning letter from FDA, a ban of the product from store shelves, recalls for the product, detention of the ingredient or product at U.S. ports, or some other enforcement action to protect the public health. For example, Prop 65 requires a warning statement for food products found to contain greater than 0.5 microgram per serving per day of lead, but the federal level prompting action based upon a safety concern is 75 micrograms per serving per day of lead if the product has conditions of use that limit it to be consumed by adults. The Prop 65 level is 150 times lower than the serving level of the federal standard. Prop 65 levels, which are below federal levels, serve no purpose other than requiring a firm to list a warning statement on products. California's Office of Environmental Health hazard Assessment also acknowledges the usefulness of the warning when it states that a “Proposition 65 warning does not necessarily mean a product is in violation of any product-safety standards or requirements.” Product safety is and should be tied to meeting good manufacturing practices established by federal statute and codified in the federal regulations (CFR parts 110 and 111 of title 21). Prop 65 is unable to ban or recall a product for failing to meet the Prop 65 level, but it does allow for “professional plaintiffs” to intimidate food firms meeting good manufacturing standards and federal limits for these same contaminants because the Prop 65 levels are much lower than federal standards. It is also unclear how natural product manufacturers can be expected to routinely test for all of the over 800 different chemicals on the Prop 65 list. Because of the expense in testing for each of the chemicals on the list, it is cheaper for firms to print the warning statement despite being below the level. Because Californians are so used to seeing and ignoring the warning statement on products and stores, it has led to desensitization by the public and outlived its usefulness as a warning statement to advise consumers of a real public health threat.

The warning statement also shows up when “chemicals” are naturally-occurring constituents of the soil the products were grown in. While Prop 65 provides an exemption from warning label requirements to exclude chemicals that have been shown to occur naturally in foods, the burden of proof is placed on the manufacturer and is impractical to meet. Most lead in food is of man-made origin, even when deposited to organic fields by weather systems in the form of rain. Under the current Section 12501, farmers and herbal product manufacturers are responsible for man-made pollutants and contaminants in the water, soil or air, no matter who or what originally caused them. Under the strict guidelines of Section 12501, the eruption of volcanic ash and resulting pollution of soil with contaminant debris would be a “man-made” event, which farmers and finished product manufacturers could not seek exemption, unless they could prove otherwise. Because the burden of proof is on the manufacturer, the manufacturer must prove that any listed chemical in the product is “naturally occurring”. In fact, an accused firm must prove that the chemical was not avoidable by good agricultural or manufacturing practices and that the chemical did not result from any known human or “man-made” activity. Proving two negatives is an unrealistic expectation to meet. The exemption, similar to Prop 65 as a whole, had good intentions but is currently misguided in its application and clearly lacks a scientific foundation for the levels requiring a warning level.

NPA also requests revision of Section 25349.10 *Exemptions from Warning Requirement*. The statement “assuming exposure at one thousand (1000) times the level in question” should differentiate the safety factor applied in traditional regulatory toxicology when human studies are available from the safety factor applied when animal data is available. Section 25349.10 should be amended to state when human studies indicate the exposure will have no observable adverse effect assuming exposure at one hundred (100) times the level in question or, when no human studies are available, the exposure will have no observable adverse effect assuming exposure at one thousand (1000) times the level in question. The current safety factor applied in Prop 65 fails to differentiate the type of evidence used. While it implies human data, it applies a safety factor typically reserved for animal studies, which apply a factor of 10 for intraspecies variation (i.e. some humans can be up to 10 times more sensitive to certain chemicals than the general population), a factor of 10 applied for interspecies variation (extrapolation from animal to human), and a factor of 10 applied for sub-chronic exposure data. A safety factor of 100 is applied for human data because interspecies variation is not a consideration.

In summary, Prop 65 places the burden of proof solely on manufacturers to prove that a warning is not required rather than on the state government to prove that a warning is required. This is in contrast to the Federal Food Drug and Cosmetic Act, which places the burden of showing something is unsafe on the government. It also requires the accused firm to prove negatives, an insurmountable and unrealistic expectation. The Prop 65 levels on common contaminants like lead, cadmium, arsenic and mercury, are typically lower than the federal provisional total tolerability intake levels established for contaminants in foods. While FDA can enforce bans or mandatory recalls because their limits are based upon a scientific body of evidence, Prop 65 levels are not based in any science. Therefore, Prop 65 limits have no purpose to protect the public. Prop 65 warnings confuse and desensitize California consumers with ubiquitous statement on foods, which are already in compliance with federal laws to ensure their identity, purity, strength, composition, and safety. Prop 65 does not establish a safety line for contaminants where a warning statement can convey meaning, but it does line the pockets of “professional plaintiffs” looking to settle for significant sums. It should be noted that products, disputed in Prop 65 lawsuits for failing to bear the warning statement, are not pulled from store shelves because of demonstration of a public health risk or harm to consumers. NPA believes that OEHHA would best serve the Agency’s prior intent by modifying this regulation with significant changes. We recommend the OEHHA work more closely with the California Department of Food and Agriculture and the U.S. FDA to modify this regulation to make sure it is in line with general principles of regulatory toxicology as well as federal and state regulatory authorities for food.

Thank you for your attention to these important matters. 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,



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CEO & Executive Director, NPA