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VIA ELECTRONIC SUBMISSION

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Re: Title 27, California Code of Regulations Proposed Repeal of Article And Adoption of New Article 6 Proposition 65 Clear and Reasonable Warnings; Comment request

Dear Sir/Madam:

The Alliance for Natural Health USA (“ANH-USA”) appreciates this opportunity to comment on the proposed regulations: *Title 27, California Code of Regulations Proposed Repeal of Article and Adoption of New Article 6 Proposition 65 Clear and Reasonable Warnings*.

As a brief background, ANH-USA is a grassroots membership-based organization consisting of healthcare practitioners, natural product companies and almost 500,000 consumer-advocate members. ANH-USA protects and promotes citizen access to information concerning the interaction between health and the environment, and the benefits of foods, dietary supplements, and lifestyle choices. Through public education, ANH-USA arms consumers with the tools they need to make informed, individualized decisions and take personal responsibility for their health.

ANH-USA has been closely following the Office of Environmental Health Hazard Assessment’s (“OEHHA”) regulatory efforts to amend the Article 6 under Prop 65. As such, we issued comments during the pre-regulatory draft phase. While OEHHA has incorporated some public comments in this recently issued proposed regulation, many of ANH-USA’s deep concerns beyond Article 6 remain unaddressed. These include:

- The abuse of the private right of action for personal profit;
- Disproportionate allocation of settlement funds;
- The lack of accountability regarding payment in-lieu of penalties; and
- The development of Safe Harbor levels for all Prop 65 chemicals.

Consequently, ANH-USA is resubmitting sections of our original comments submitted on November 11, 2014, that still require attention from OEHHA. We respectfully request that OEHHA incorporate our recommendations in the regulatory process.

Sincerely,



Gretchen DuBeau, Esq.
 Executive and Legal Director
 Alliance for Natural Health USA

Comment

ANH-USA is highly supportive of the intent of Prop 65, to prevent public exposure to carcinogenic and reproductive toxins, but we are cognizant of the problematic implementation and enforcement of the law.

Opportunistic Private Plaintiffs:

While the intent of the law is commendable, our concern is that the law is being exploited by private plaintiff attorneys. An analysis of the distribution of costs from Prop 65 settlements reveal that private plaintiffs, not the public at large, are benefiting the most. Almost all Prop 65 cases are brought by a small handful of private plaintiff firms profiting from the law. Besides the exorbitant attorney costs and fees, they are able to extract further bounty through “payment in lieu of penalties,” ostensibly to further the intent of the law, but in actuality there is not accounting for how this money is spent. At the same time, many private plaintiffs choose to limit the civil penalties as much as possible because they are only allowed to keep 25% of the amount, while the other 75% is for the AG’s office to put toward enforcing prop 65 and other environmental laws. Therefore, private plaintiffs apportion a greater share of the settlement agreement toward “payment in lieu of penalties,” and attorney costs and fees, which have no limitation.

The distribution of penalties in 2012 paint this picture clearly: Attorney costs and payment in lieu of penalties make up a disproportionate share of the private plaintiff agreement, especially as compared to cases settled by the AG and district attorneys.

	Attorney Fees	Civil Penalties		Payment in Lieu of Penalties	Total
		State of California (75%)	Plaintiffs (Bounty Hunter) (25%)		
Breakdown of costs from 397 cases brought by private enforcers.					
Amount	\$14,579,592.53	\$2,265,014.66	\$755,004.89	\$2,836,159.53	\$20,435,771.60
Percentage	71.34%	11.08%	3.69%	13.88%	100.00%
Breakdown of costs from 33 cases brought by AG/District Attorneys					

Amount	\$829,674.00	\$1,005,576.00			\$1,835,250.00
Percentage	46.62%	54.79%			100.00%

Naturally occurring Prop 65 chemicals

In particular, nutritional supplement companies have been disproportionately targeted by opportunistic Prop 65 lawsuits. They make up a significant percentage of the Prop 65 notices (indicating potential enforcement action) issued each year:

- In 2013, 61 of 1094 notices total were sent to supplement companies.
- In 2012, 86 of 911 notices.
- In 2011, 132 out of 1079 notices.
- In 2010, 172 out of 788 notices.

The most commonly cited Prop 65 chemicals for dietary supplements is lead, which made up 96% of enforcement actions between 2005 to 2012. Unfortunately lead is highly prevalent in the natural environment, and unavoidably end up in high quality supplements (often at very low levels) that contain natural ingredients. This makes even the conscientious dietary supplement company an easy target for Prop 65 enforcement action.

While there is an exemption for exposures resulting from Prop 65 chemicals that naturally occur in food (including dietary supplements), the evidentiary bar is very high and the burden is on the food company. In fact, the prevalence of lead in the natural environment has been recognized in a number of settlements, including the “Warner-Lambert” settlements, in which the AG fixed naturally occurring allowances for lead above the very low Prop 65 threshold.

However, only supplement companies party to the settlement can rely on the higher thresholds, and while some prosecutors allows non-parties to employ the allowances, others do not. The AG has insisted that only parties to a consent judgment may rely on the allowances.

Consequently, many supplement companies face the unhappy choice of placing a warning on their product and deterring their health conscious customer base or making themselves vulnerable to a lawsuit. Our concern is that consumers may avoid high quality supplements because of a generic Prop 65 warning without realizing that most natural ingredients contain lead, and that in some cases the benefits of supplementation may in fact outweigh the risks.

Safe harbor levels and uncertainty for businesses and consumers:

Of over the 800 Prop 65 chemicals listed, OEHAA has established safe harbor levels for only about half. So companies are expected to know whether they are exposing the public to any listed contaminants in dangerous levels, but the state doesn’t know what those safe levels are. This creates uncertainty for business, and dilutes the meaningfulness of warnings for consumers in the absence of an established standard.

Recommendations:

- **Cap or limit attorney’s fees:** Given that attorney fees make up a significant amount of the costs associated with Prop 65 cases, which is neither to the benefit of public or the environment, they

should be capped, or at the very least, considered reasonable in light of the totality of the circumstances and subject to review by the court.

- **Accountability regarding payment in lieu of penalties:** There should be limits to the percentage of the settlement that is apportioned towards payment in lieu of penalties, and there should be a transparent auditing system in place to track how these funds are utilized. These penalties should not be excessive and should be clearly connected to remediating the related exposure concern. They should never be utilized to pay attorney fees or bring additional legal actions.
- **Greater disclosure of plaintiff's information:** The plaintiff must agree to share information in good faith with the defendant upon request, including allegations of the notice, studies (or other data relevant to the allegations), terms on which the action may be resolved or averted.
- **Streamlined process to qualify for the Warner-Lambert threshold levels:** There should be a process in place to allow for supplement companies that are able to document their manufacturing processes to preemptively apply for inclusion in the higher Warner-Lambert threshold levels for lead.
- **Develop "safe harbor levels" for all Prop 65 chemicals:** OEHAA should develop safe harbor levels for all Prop 65 chemicals. OEHAA should further work with industry and the public to ensure that the safe harbor levels protect public safety, while also avoiding ubiquitous warnings that dilute their meaning by making the safe harbor levels too low.

Conclusion:

ANH-USA supports efforts to amend Prop 65 warning regulations in order to maintain the true intent of the law to provide effective warning to consumers and the public at large regarding hazardous exposures to cancerous and reproductive toxins. However, we urge OEHAA to address all our concerns to ensure comprehensive Prop 65 reform. This will protect companies from unnecessary enforcement via frivolous lawsuits, ensure that the distribution of settlements serve the intent of the law, and guarantee that the public is able to receive meaningful and accurate warning information to reduce exposure to environmental toxins.