



January 21, 2022

Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
1001 I Street, 23rd Floor  
P. O. Box 4010  
Sacramento, California 95812-4010

Via electronic submission to: <https://oehha.ca.gov/comments>

RE: Public comments to amendments to Article 6 Clear and reasonable warnings – short-form warnings

Dear Ms. Vela,

The following comments are submitted by the American Herbal Products Association (AHPA), the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products.

AHPA has prepared these comments in response to the December 13, 2021 OEHHA Notice of Proposed Rulemaking (December 13<sup>th</sup> Notice) titled “Proposed Amendments to Article 6 Clear and Reasonable Warnings.”<sup>1</sup> In this notice, OEHHA summarizes the amendments that have been made to its initial Notice of Proposed Rulemaking from January 8, 2021 (January 8<sup>th</sup> Notice). These amendments include, but are not limited to the following:

- Increases the maximum label size for short form warnings from 5 square inches to 12 square inches (sq in) to accommodate concerns expressed in public comments to the January 8<sup>th</sup> Notice, while still limiting use of the short-form warnings to packages with limited available label space for consumer product information that would not easily accommodate the full warning;
- Restores the option to use the short form warning content in online warnings or in a catalog;
- Provides for additional signal word options and a safe harbor warning option.

AHPA submitted comments to the January 8<sup>th</sup> Notice on March 29, 2021 expressing concern about significant revision of the short form warning format relatively soon after the option was promulgated as part of the 2016 warning requirement revisions, which became effective in 2018. AHPA’s members marketing products in California will be directly impacted by the proposed changes issued by OEHHA, and these additional comments to OEHHA’s amended proposal are

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<sup>1</sup> Available at <https://oehha.ca.gov/media/downloads/cnrn/noticeshortformreg121321.pdf>.

offered on their behalf. AHPA has not offered comments to all elements in the December 13<sup>th</sup> Notice; absence of comments on any element or section of the amended proposal should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

**Restriction to labels of a total of 12 square inches or less**

OEHHA’s amended proposal limits the use of short-form warnings to product labels for which the “surface area of the product label available for consumer information is 12 square inches or less,” and that cannot accommodate a full size warning. AHPA appreciates that OEHHA considered the public comments from AHPA and other organizations regarding the introduction of a size limitation to the use of the short form warning. In its March 29, 2021 comments, AHPA noted that FDA<sup>2</sup> defines small food packages as those with less than 12 sq in of total surface area available to bear labeling, so the OEHHA proposal is now consistent with one recognized standard of a “small label.”

The short-form warning format is useful to AHPA's members since many of the products our members market have relatively small labels presented on packages and containers of dietary supplement dosage forms such as tablets, capsules, soft gels, and gummies, as well as other products such as cosmetics and personal care products. Marketers of these products must comply with numerous other regulations that mandate specific labeling content and how that content is presented, such as the federal labeling regulations for dietary supplements<sup>3</sup> or the warning that manufactured cannabis products marketed in California are required by the Manufactured Cannabis Safety Branch (MCSB) to bear in their labeling.<sup>4</sup> The option to use the current short-form warning format provides needed flexibility that allows marketers to comply with Proposition 65 as well as other regulatory labeling obligations.

While AHPA finds the amended limitation to less than 12 sq in of labeling to be more appropriate than the initial proposed limitation of less than 5 sq in, we do not expect this amended limitation to adequately accommodate the majority of product marketers in the industries in which our members are active. For example, the 12 sq in limitation will not be sufficient to accommodate the common package size of a 2 in diameter bottle with a label height of 2 in (12.5 sq in of labeling). For reference, such a package and label size combination would typically contain up to 60 capsules of a dietary supplement product. Thus, it appears that the increase to a limitation of 12 sq in of labeling will still require the majority of companies in our industry to transition to full size warnings to remain compliant.

Given that any product marketer currently using the short form warning will be required to make changes to their Proposition 65 labeling practices (to either revise current short form warning

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<sup>2</sup> US FDA. Guidance for industry: A food labeling guide. January 2013.

<sup>3</sup> 21 CFR Part 101.36 Nutrition labeling of dietary supplements, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101>

<sup>4</sup> California Code of Regulations, Title 17 Division 1 Chapter 13. Manufactured Cannabis Safety, §40404. Labeling Requirements: Pre-Rolls and Packaged Flower and §40408. Informational Panel Labeling Requirements.

content and/or transition to the full size warning format), AHPA requests that the proposed changes allow for a three year transition period in place of the currently proposed one year phase in. The transition period provided by OEHHA when the short-form warning format was originally introduced was two years, during which time companies undertook significant financial investments to conform to the new warning requirements. If these proposed changes are instituted, a transition period of three years is necessary as many companies would be making these same label changes as they continue to operate under emergency orders and deal with the challenges of labor shortages and supply chain issues due to the ongoing COVID-19 pandemic.

AHPA noted in its March 29, 2021 comments that the original OEHHA proposal lacked an assessment of the financial impact of the introduction of a label size limitation on product marketers that are currently providing compliant safe harbor warnings using this option. The revised proposal from OEHHA does not address this omission. For the dietary supplement industry alone, AHPA estimates this cost to be in the millions of dollars based on information obtained from a cross-section of our membership that utilize the short-form warning. Even companies that may be able to continue using the short form warning under the proposed size limitation will have to revise their labels due to the new requirement to identify at minimum one chemical name of a carcinogen, a reproductive toxin, or both as applicable, in the proposed warning requirements.

#### **Concluding statement**

In summary, AHPA strongly recommends that OEHHA rescind the proposal to change the short form warning format, as requested in its comments dated March 29, 2021.

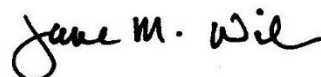
If the proposal cannot be tabled, AHPA requests that OEHHA extend the transition period for compliance with the proposed changes to the short-form warning provisions to provide for a three year phase-in.

AHPA greatly appreciates the opportunity to present comments during this public comment process. We welcome any questions that may arise from AHPA's comments.

Respectfully submitted,



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