

California Nutrition Council

A nonprofit association, established in 1970, of nutrition professionals from government agencies, private organizations, and academic institutions working toward effective nutrition policy for California

CNC

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Dietary Supplement Stakeholder Meeting
Food and Drug Administration
Testimony submitted on behalf of the California Nutrition Council
(CNC)
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My name is Rita Mitchell. I am the President of the California Nutrition Council, a nonprofit organization of approximately 150 nutrition professionals and other individuals representing government agencies, universities and colleges, professional associations, private organizations, the food industry, and consumer groups. This diverse membership allows CNC to present a unique viewpoint to the dietary supplement issue because our members work directly with consumers; with programs to educate consumers; and with scientific, peer-reviewed research evaluating nutritional needs, safety issues and consumer understanding.

CNC applauds FDA for providing this opportunity to speak out publicly about the inadequate system of assuring consumer safety with respect to dietary supplements. The first of the specific questions you raise asks for objectives, that an overall dietary supplement strategy should address, "in addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled." We believe that many dietary supplements available continue to be unsafe and misleadingly labeled. We would be satisfied if consumers did have access to safe dietary supplements

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that are truthfully and not misleadingly labeled. Under the current laws, dietary supplements do not have to be proven safe or effective **before** they are marketed. Ideally, the law should be changed to correct this situation and we would support any legislative effort to do so. Consumers need assurances that products are safe and that claims are substantiated by valid scientific research.

CNC members in clinical practice have described experiences in which individuals have delayed conventional treatment of serious illnesses in favor of taking dietary supplements. Information on the package label led them to believe that these products would help them. In fact, the supplements contributed to severe disability or even death. Consumers must be protected and they should be informed that current law does not guarantee that all dietary supplements offered for sale are safe and effective.

We strongly believe that ensuring public safety should be FDA's top priority. We recommend that FDA mount a massive public education campaign, similar to the anti-tobacco campaign, to encourage consumers to learn all they can about the dietary supplements they take.

In preparing this testimony, I have spoken to many consumers and health professionals. Most of them were not aware of the provisions of the Dietary Supplement Health and Education Act (DSHEA). They were horrified to learn that products can be marketed before they are proven safe and effective; that they are not required to meet the rigorous safety and quality standards of food additives and drugs. They were also dismayed to learn that manufacturers can sell products claiming to cure all kinds of illnesses or ailments, when in fact, there is no proof that the products will cure illnesses and may even be harmful or deadly. Consumers have a right to know of the potential risks associated with intake of dietary supplements.

CNC recommends that the FDA establish specific criteria for a **voluntary** approval process, allowing products to bear a seal of FDA approval for safety and effectiveness. CNC members would be willing to contribute expertise to the development of such criteria.

We recommend strengthening the adverse event reporting system. This should be part of the massive consumer education campaign—to let consumers know the importance of reporting adverse events, plus information about how to easily report these events. **FDA must improve the follow-up process when adverse events are reported.** We urge you to enforce the law to stop the rampant proliferation of dietary supplements with unfounded claims.

In addition, as the part of the adverse event reporting system, we suggest that there be a **mandatory** reporting requirements to the Centers for Disease Control and Prevention by physicians and other health professionals who learn of documented cases of adverse events related to dietary supplements.

CNC recommends that FDA require specific written information be provided with dietary supplements, including botanicals. This information should be standardized so consumers can make comparisons and informed decisions. Required information should include, but not be limited to:

- active ingredients;
- directions for use including maximum suggested level per designated period of time;
- interactions with prescription medications and over-the-counter drugs;
- toxicity levels;
- caution statements when appropriate for vulnerable groups such as pregnant and lactating women, children, the elderly, and persons with compromised immune systems;
- and shelf life and storage conditions.

There is much still to be learned in the area of dietary supplements. CNC supports scientific research on the safety and effectiveness of dietary supplements, especially those for weight loss and other widely used products.

In summary, CNC members believe that the public has the right to dietary supplements that are safe, effective, and appropriately labeled. They have the right to information they need to make decisions based on sound scientific research. CNC members have expertise in nutritional science and consumer education. We stand ready to assist the FDA in any way we can to achieve these goals and objectives.

Thank you for your attention and for allowing me to provide this testimony.