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Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

**Oral Testimony of the Consumer Healthcare Products Association
to the White House Commission**

on

Complementary and Alternative Medicine Policy

Minnesota Town Hall Meeting

Hubert H. Humphrey Institute

301 19th Avenue South

Minneapolis, MN

on

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Director of Science & Technology**

The Consumer Healthcare Products Association is a 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research, and advertising sectors of the self care industry.

We have been intimately involved in the regulatory development of the industry, commenting and facilitating dialogue and activities relating to safety, labeling, quality and other matters affecting the production and distribution of dietary supplements. Just last week our Association adopted eight voluntary programs on dietary supplements relating to manufacturing, labeling, and formulation of safe and high quality products, adding to our programs already in place on St. John's wort, ephedra, and use of dietary supplements during pregnancy.

My remarks address two aspects of the questions that were set forth in the announcement of this meeting: (a.) health professional and consumer access to safe and effective dietary supplements¹; and (b.) educational issues relating to complementary and alternative medical practitioner use of dietary supplements.²

¹ WHCCAMP Registration Form Question 2.a.: How can access to safe and effective CAM practices and interventions be improved?

² WHCCAMP Registration Form Question 3: Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine.

First, on safe, effective, high quality dietary supplements, our call is to the White House Commission as well as health professionals to support the Congressional appropriations process soon to be initiated by the Center for Food Safety and Applied Nutrition (CFSAN). Consumers, health professionals and industry need an FDA that is adequately funded to appropriately and reasonably implement the spirit and intent of the Dietary Supplement Health Education Act, or DSHEA. Along these lines, let me share the following points:

- FDA and the Federal Trade Commission have the tools they need to adequately regulate dietary supplements^{3 4}.
- FDA has put in place the strategic management tools to justify allocations of increased funding⁵, including the development of its long range plan and annual priorities through extensive stakeholder input, as well as use of a year-end report card process to define the extent it met its priorities that year.
- This Spring, FDA will provide Congress with two important fiscal reports – one pertaining to the how much it spent on dietary supplement regulation in 2000; another pertaining to the funding needed to implement its long-range strategic plan. This is the start of the appropriations process.

Our message is, the White House Commission should report to the new Administration the clear need to push for the level of appropriations necessary for CFSAN to fairly and reasonably implement DSHEA, thereby allowing FDA to use its existing substantial enforcement tools to regulate dietary supplements, in order to ensure safe, effective, high-quality dietary supplements for consumer and health professional use⁶.

Further to this point, the Commission has an opportunity to support FDA in achieving its priority “A” list in its 2001 Annual Priorities⁷ (Attachment A), including especially the publication of Good Manufacturing Practices, the finalization of which is necessary before FDA can have an effective field presence through an enforcement program. Additionally, FDA proposes to develop a master research plan for dietary supplements, and the White House Commission should recommend that this be developed with full stakeholder input, including that from CAM practitioners.

Other “A” priorities should be evaluated by the Commission as possible areas for additional recommendations. A member of the Commission should be tasked with this activity, and I have appended a copy of FDA’s long-range strategic plan and 2001 annual priorities for this purpose (Attachment B).

³ Soller, R.W.: Regulation in the Herb Market: The Myth of the Unregulated Industry. *Herbalgram* Feb.-Mar., 2000.

⁴ FDA Commissioner Jane E. Henney, M.D. before the House Committee on Government Reform, March 25, 1999: “FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA.”

⁵ Levitt, J.: Formal address to the CHPA Annual Meeting, *Nutritionals 2001*, Anaheim, CA, 1/31/01.

⁶ Soller, R. W.: Will FDA Get the Funds to Effectively Regulate Dietary Supplements? *JANA* March, 2001.

⁷ See Attachment B: Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments [65 *Federal Register* 39415-39416 (6/26/2000)].

Second, with respect to the educational aspects of CAM practitioners and dietary supplements, we recommend a strategic perspective on the use of collaborative educational partnerships between the National Institutes of Health (i.e., National Center for Complementary and Alternative Medicine and Office of Dietary Supplements) and professional groups. For example, we are aware that the University of Minnesota and the American Nutraceutical Association are developing a collaborative approach to certifying licensed healthcare practitioners in dietary supplement use. Such certification brings quality to the informational aspects of product use, and special funding vehicles should be developed to encourage such upgrading of the knowledge base of health professionals.

Thank you.

Attachments A FY 2001 CFSAN Program Priorities: www.cfsan.fda.gov
B Center for Food Safety and Applied Nutrition: Dietary Supplement Plan: Ten-Year Strategy, www.cfsan.fda.gov