



Council for Responsible Nutrition

The Science Behind the Supplements®



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**DIETARY SUPPLEMENT INDUSTRY CALLS FOR OVERHAUL OF
FDA'S NDI DRAFT GUIDANCE**

—Industry associations join together to request revisions, a more reasonable guidance—

WASHINGTON, D.C., *December 6, 2011*—The dietary supplement industry's trade associations—the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), the Natural Products Association (NPA), and the United Natural Products Alliance (UNPA)—joined together to call for an overhaul of the Food and Drug Administration's (FDA) Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, which in its current form undermines both the letter of the law and the intent of the Dietary Supplement Health & Education Act (DSHEA) of 1994.

The Draft Guidance issued by FDA in July, if implemented and enforced by FDA, would burden industry, placing unreasonable requirements on business, especially smaller firms, and create unreasonable barriers of entry for newer market entrants, without any related benefits for consumers, according to the five industry trade associations. While the groups submitted separate comments to reflect their own membership priorities, the five associations stressed that FDA should focus on the common themes in their respective submissions, rather than look for points of disparity as indicating any substantive differences of

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opinion among the groups. “We are all committed to seeing a substantial overhaul of the draft guidance and are united in our common belief that the document is overreaching and contravenes DSHEA,” the five associations announced jointly.

Common key issues identified in the draft guidance by the trade groups representing the dietary supplement industry, if implemented and enforced by FDA, include:

- Requiring submission of a notification for virtually every product that contains an NDI from every manufacturer;
- A shift in the burden of proof that an ingredient is not an NDI from FDA to individual companies;
- FDA’s claim that there are no authoritative lists of “grandfathered” ingredients that can be used to establish that a dietary ingredient is an Old Dietary Ingredient (ODI), which dismisses the relevance of “grandfathered” lists submitted by the trade associations in 1996-1998 for establishing that dietary ingredients are pre-DSHEA ingredients;
- Misinterpreting the meaning of the term “*chemically altered*,” which significantly expands the category of ingredients that would constitute an NDI;
- Stating that human synthesized constituents of botanical ingredients are different from those synthesized by the plant; and
- Imposing a level of data necessary to demonstrate the safety of an NDI similar to what is required for food additives, a standard already rejected by Congress and the courts.

The trade associations call on FDA to carefully consider the comments to the docket it has received and to issue guidance that addresses these serious concerns. The associations also urged for a timely response from the agency to provide industry with clarity and direction as the industry attempts to comply with the requirements of the law, and the associations offered to work with FDA to achieve that goal.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal and botanical products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products, including foods, dietary supplements, cosmetics, and non-prescription drugs. Founded in 1982, AHPA's mission is to promote the responsible commerce of herbal products. Website: www.ahpa.org.

The Consumer Healthcare Products Association (CHPA) is the 129-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements. Information on the Association can be found at www.chpa-info.org.

The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 75+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN's Code of Ethics. Visit www.crnusa.org.

The Natural Products Association (NPA), founded in 1936, is the largest and oldest non-profit organization dedicated to the natural products industry, representing more than 10,000 retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. As the leading voice of the natural products industry, the NPA's mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. Visit www.NPAInfo.org.

The United Natural Products Alliance (UNPA) is an association representing many leading dietary supplement, functional food and analytical companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability. Founded in Utah in 1992, UNPA was instrumental in the passage of the 1994 Dietary Supplement Health and Education Act (DSHEA) and continues to take a leadership position in regulatory issues and industry best practices. You may visit our website at www.unpa.com