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CRN CALLS FOR FDA'S WITHDRAWAL OF NDI DRAFT GUIDANCE

WASHINGTON, D.C., *December 2, 2011*—The Council for Responsible Nutrition (CRN), the dietary supplement industry's leading trade association, today called on the Food and Drug Administration (FDA) to withdraw the agency's New Dietary Ingredient (NDI) Notification Draft Guidance, stating "...the agency's attempt to redefine the NDI notification process...contradicts the letter and spirit of DSHEA." The [comments](#) were submitted to the docket and were filed jointly with the Consumer Healthcare Products Association (CHPA).

According to CRN President & CEO Steve Mister, "The draft guidance would essentially undo nearly two decades of agency practice and policy that began with DSHEA's passage. CRN and others in the industry have been calling on FDA to provide clarity through this draft guidance, and responsible industry fully supports a reasonable guidance that provides directions for filing NDI notices within the legal framework of DSHEA. However, this guidance does not answer that call."

According to the associations' comments, the draft guidance would impose significant and unnecessary burdens on the industry, stifle innovation, and curtail industry growth—without conferring additional safety benefits to consumers. Added Mr. Mister, it would increase barriers to market entry for new companies and ingredients and deny consumers access to the wide variety of safe and beneficial products on which they rely for good health.

In addition, other specific areas of concern about the draft guidance include:

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- the imposition of an unreasonable burden of proof on industry to establish an ingredient's non-NDI status;
- the inability for the supplement industry to market nature-identical synthetic botanicals;
- the requirement of unnecessary and duplicative NDI notifications;
- the inappropriate expansion of the number of dietary ingredients defined as NDIs;
- and the morphing of the NDI notification process into a premarket proof of safety requirement mirroring the requirement for a food additive.

“In its current form, the draft guidance is inappropriate and unworkable,” said Mr. Mister. “We look to FDA to strongly consider these—and other—comments and to act swiftly to provide us with a workable document that we can wholeheartedly support.”

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Note to Editor: 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.