

**FOR IMMEDIATE RELEASE**

Contact: Trainor Walsh, 202-204-7671

**TOP LAWYER QUESTIONS LEGAL MERITS OF NDI DRAFT GUIDANCE
—CRN/VIRGO Webinar Pairs FDA Representatives with
Industry Experts to Discuss Controversial Document—**

WASHINGTON, D.C., *September 29, 2011*—The Food and Drug Administration’s (FDA) New Dietary Ingredient (NDI) draft guidance may not stand up in a court of law if finalized and enforced as is, suggested an attorney panelist to an estimated audience of 250 participants during a recent webinar analyzing the controversial document. The September 14 webinar was co-hosted by the Council for Responsible Nutrition (CRN) and VIRGO, and is now available for a limited time for purchase on-demand.

CRN’s Duffy MacKay, N.D., moderated the webinar which included four speakers: FDA’s Daniel Fabricant, Ph.D., director, Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (CFSAN); FDA’s Dan Levy, Ph.D., supervisor, New Dietary Ingredient Review Team, Division of Dietary Supplement Programs, CFSAN; James E. Hoadley, Ph.D., senior consultant, EAS Consulting Group and a 20-year FDA veteran; and Ashish Talati, J.D., M.S., RAC, partner, Amin Talati.

The two FDA officials provided an overview of the draft guidance, discussed FDA’s reasoning and rationale for the draft guidance, and explained the process the agency goes through during New Dietary Ingredient Notification reviews. Dr. Hoadley offered his best practices for submitting NDI Notifications and Mr. Talati shared his legal perspective of the draft guidance, including his opinion that the draft guidance may not withstand judicial review; specifically referencing an established legal test for review of agency actions that he believes undercuts FDA’s position.

-more-

According to CRN’s Dr. Duffy MacKay, “We’re grateful for the time and expertise provided by all four speakers. Our industry requested an NDI draft guidance from FDA to help clarify the law and level the playing field; however, this draft guidance overreaches and attempts to perform an end run around the original intent of the Dietary Supplement Health and Education Act. We hope that FDA is serious about listening to industry concerns about the document and will moderate its interpretation to incorporate many of our concerns about the legal requirements for NDIs.”

The two-hour webinar is available for [purchase](#) on-demand until its December 21 expiration (\$149 for CRN members; \$199 for non-members). A pre-recorded bonus hour with a panel of legal experts—Michelle C. Jackson, associate, Venable, LLP; Sarah Roller, J.D., R.D., M.P.H., partner, Kelley Drye, LLP; Ashish Talati, J.D., M.S., RAC, partner, Amin Talati, LLC; Steve Mister, Esq., president & CEO, CRN—can also be purchased with the webinar at an additional cost of \$99.

In addition to the webinar, VIRGO will hold a town hall discussion on the topic at its annual trade show [Supply Side West](#), which will be held October 10-14 in Las Vegas. CRN will hold a wrap-up session at [The Conference](#), “NDIs—What’s Our Next Move?” to explore next steps. The Conference will be held in Rancho Palos Verdes, Calif., October 19-22 at the Terranea Resort.

To learn more about purchasing the webinar, future CRN/VIRGO webinars, or *The Conference*, please contact CRN’s Trainor Walsh at twalsh@crnusa.org or visit or www.crnusa.org. To learn more about Supply Side West, please contact VIRGO’s Jon Benninger at jbenninger@vpico.com or visit [Natural Products INSIDER](#).

###

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.