

O Council for Responsible Nutrition 1828 L Street, NW, Suite 510 • Washington, DC 20036-5114 (202) 204-7700 • fax (202) 204-7701 • www.crnusa.org





August 3, 2011

Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: REQUEST FOR EXTENSION OF COMMENT PERIOD. Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, Availability. 76 Fed. Reg. 39111 - 39112 (July 5, 2011). Docket No. FDA-2011-D-0376

Dear Sir or Madam:

The American Herbal Products Association (AHPA¹), the Consumer Healthcare Products Association (CHPA²), the Council for Responsible Nutrition (CRN³), the Natural Products Association (NPA⁴), and the United Natural Products Alliance (UNPA⁵) appreciate the opportunity to provide comments on the Agency's draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," released on July 5, 2011 (76 Federal Register 39111-39112). We applaud FDA for the release of this document and welcome the opportunity to provide comments with respect to the draft guidance.

The Agency's draft guidance for industry on new dietary ingredient (NDI) notifications is thorough and complex, thus requiring an in-depth review by stakeholders. In the July 5th Federal Register notice, FDA allowed for a 90-day public comment period. However, members of our respective organizations believe additional time is needed to adequately prepare meaningful feedback for the Agency's consideration. Therefore, on behalf of AHPA, CHPA, CRN, NPA, and UNPA members, we are requesting that FDA extend the submission deadline by an additional 45 days (i.e., November 17, 2011).

Consumer Healthcare Products Association

900 19th Street, NW, Suite 700 Washington, DC 20006

т 202.429.9260 г 202.223.6835 www.chpa-info.org

¹ AHPA is a U.S.-based trade association, established in 1982, representing growers, manufacturers, and marketers of herbal and botanical ingredients and products (www.ahpa.org).

² CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter medicines (<u>www.chpa-info.org</u>). ³ The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association

representing dietary supplement industry manufacturers and ingredient suppliers. (www.crnusa.org).

⁴ Founded in 1936, the Natural Products Association is the nation's largest and oldest non-profit organization dedicated to the natural products industry. (www.npainfo.org).

⁵ UNPA is an association of dietary supplement and functional food companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability (www.unpa.com).

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Thank you for considering our request. Please feel free to contact Dr. Marcia Howard should you have any questions.

Sincerely,

Marcia D. Howard

Marcia D. Howard, Ph.D. Senior Director, Regulatory & Scientific Affairs Consumer Healthcare Products Association 900 19th Street NW, Suite 700 Washington, DC 20006 Phone: 202-429-9260 Email: mhoward@chpa-info.org

Michael McGuffin President American Herbal Products Association

D. Mart

Douglas Mackay, N.D. Vice President, Scientific & Regulatory Affairs Council for Responsible Nutrition

Cara Welch

Cara Welch, Ph.D. Vice President, Scientific & Regulatory Affairs Natural Products Association

Harry B. Rice, Ph.D. Vice President, Regulatory & Scientific Affairs United Natural Products Alliance

cc: Daniel Fabricant, Ph.D.; Corey Hilmas

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