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

December 4, 2012

The Honorable Margaret Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 1
Room 2217
Silver Spring, MD 20993

Barbara O. Schneeman, PhD
Director
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Commissioner Hamburg and Dr. Schneeman:

Thank you for your letter of November 19th responding to CRN's submission to FDA Commissioner Margaret Hamburg on the legal status of synthetic botanical constituents as dietary ingredients. I appreciate your time to review CRN's submission and to prepare the response on behalf of the Commissioner.

However, CRN is dismayed by the cursory explanation FDA has provided and the apparent intransigence of FDA with regard to its legal interpretation of section 201(ff)(1) of the Food Drug and Cosmetic Act (21 U.S.C. §321(ff)(1)). The agency's apparent position, as described in your letter – that a synthetic copy of a botanical ingredient would not qualify as a botanical "constituent" under subsection 201(ff)(1)(F) unless it can be bootstrapped through some other subsection of section 201(ff), such as the "dietary substance" provision of (1)(E) – is completely without legal basis. CRN thoroughly addressed the legal support for our position in our 27 page submission. The agency's viewpoint runs completely counter to the language and history of the Dietary Supplement Health & Education Act (DSHEA), as we have pointed out on numerous occasions to the agency – each time without receiving a substantive response from FDA as to the legal authority upon which it bases its view. Consider the following points articulated in CRN's submission:

- FDCA section 201(ff)(1)(A) through (E) do not make any distinction between synthetic and naturally occurring dietary ingredients and FDA has long permitted synthetic versions of those substances. FDA fails to explain why it believes it can read an implied

limitation into subsection (F) that would prohibit synthetic versions of these dietary ingredients.

- Congress has expressly permitted synthetic forms of other dietary ingredients (*see* FDCA §411), and FDA's own regulations explicitly prohibit the marketing of a natural vitamin as being superior to a synthetic one; FDA fails to offer explanation why a synthetic version of a botanical constituent should be categorically excluded from use as a dietary ingredient in contrast to the inclusive nature of the Act and FDA's regulation in other contexts.
- Dietary ingredients are defined by their biological activity, not by their source. Thus, provided that the synthetic substance is indeed chemically equivalent to its natural twin, there is no basis for the disparate treatment of synthetic compounds that are identical to naturally-occurring ones. Indeed, FDA's own pronouncements with respect to ephedra articulated that synthetically-produced ephedrine is "chemically indistinguishable" from ephedra, and thus, naturally-occurring ephedra could not be treated differently than its synthetic counterpart.
- The legislative history of DSHEA makes clear that historic use in food or drink is not required for a dietary ingredient. This directly contradicts FDA's apparent opinion that synthetic constituents of botanicals must satisfy some other prong of the section 201(ff)(1) definition, such as the (1)(E) (the "dietary substance" provision), in order to qualify as a dietary ingredient. FDA's view finds no basis in the legislative history of DSHEA or the legislative intent of its drafters.

Recently, the industry has observed FDA's efforts to enforce this viewpoint through a variety of actions (detailed in our October 22, 2012 submission), despite its assuring members of Congress earlier this spring that it would refrain from enforcement of this controversial view until it more fully explained how it reached this interpretation of the statute. Now, that legal error is being compounded even further by the agency's recent attempt to read into subsection (ff)(1)(E), an additional requirement that the dietary substance must itself have been "commonly used as a food or drink." (*See, e.g.*, FDA's warning letter to Regeneca on August 28, 2012, at http://www.fda.gov/ICECI/EnforcementActions /WarningLetters/2012/ucm318069.htm) The impact of that interpretation would be to further limit the universe of dietary ingredients because the agency apparently believes that it is not enough that the dietary substance is present in a food, but that consumers intentionally used the particular constituent itself "as a food or drink." We see no more basis in the law for that interpretation of subsection (1)(E), than we do for the agency's view on synthetic constituents of botanicals in (1)(F).

Unfortunately, your statement that you hope the agency's response to CRN's submission "helps clear up any confusion on this issue," does not clear up the confusion. CRN and its members are not confused as to the plain meaning of DSHEA or the intent of the drafters of DSHEA as to what was envisioned when the law was enacted. The confusion is how FDA can repeatedly espouse a viewpoint that is not supported by the law, the legislative history or the agency's own precedent, and continue to refuse to explain itself or offer legal support for that position.

We had hoped the FDA would seize this opportunity to re-evaluate its position and clear up the apparent misreading of the law within the agency. While we appreciate your time to respond, the issue is still unresolved. Accordingly, it is evident that CRN must prepare for other opportunities and venues to make the plain meaning of the law apparent to the agency as appropriate. Thank you again for your time and attention to this matter.

Sincerely yours,

Steve Mister
President & CEO

cc: Elizabeth H. Dickinson, Esq., Chief Counsel, FDA
Michael Landa, Esq., Director, Center for Food Safety & Applied Nutrition
Daniel Fabricant, PhD, Director, Office of Dietary Supplement Programs
Michael Taylor, Esq. Deputy Commissioner for Foods, Center for Food Safety & Applied Nutrition
The Honorable Tom Harkin
The Honorable Orrin Hatch