DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

NOV 19 2012

Mr. Steven M. Mister
President and Chief Executive Officer
Council for Responsible Nutrition
1828 L Street, NW, Suite 510
Washington, DC 20036-5114

Dear Mr. Mister:

Thank you for your letter of October 22, 2012, co-signed by two of your colleagues, regarding the legal status of synthetic botanical constituents as dietary ingredients. Based on the content of your letter, we are adding your letter to the docket for the new dietary ingredient (NDI) draft guidance. We are also adding our response letter to the docket and sending the same letter to the co-signers of your letter.

In addition, we would like to take this opportunity to clarify our position on recognizing synthetic copies of botanical constituents as dietary ingredients. Although we do not regard synthetically produced ingredients as botanical dietary ingredients under section 201(ff)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321(ff)(1)(C)) because they were never part of a plant, that does not prevent such ingredients from being dietary ingredients under other parts of section 201(ff)(1) if they meet the definition for another type of dietary ingredient. For example, a synthetic copy of a botanical constituent would be a dietary ingredient under section 201(ff)(1)(E) of the FFDCA (the "dietary substance" provision) if, like several substances discussed in your letter (e.g., vanillin and cinnamates), it is used as an ingredient in the conventional food supply. We trust this helps clear up any confusion on this issue.

In revising the draft guidance, we plan to address synthetic ingredients in more detail and clarify our position on several issues. We will publish a notice of availability in the *Federal Register* after we complete the revisions to the draft guidance.

Sincerely,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutrition, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition