United States Senate
WASHINGTON, DC 20510

December 22, 2011

Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
109903 New Hampshire Ave.
Building 1, Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As the principle authors of the Dietary Supplement Health and Education Act of 1994 (DSHEA), we write to express our significant concern regarding the Food and Drug Administration's (FDA) draft guidance for industry entitled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," which the agency published on July 5, 2011. For the reasons outlined below, we urge the FDA to withdraw this guidance and begin work on a new draft that will provide needed clarification on what constitutes a New Dietary Ingredient (NDI), but does not undermine the balance Congress struck in DSHEA to provide consumers with access to safe, affordable dietary supplement products.

When Congress included language in the Food Safety Modernization Act (FSMA) directing FDA to clarify when a dietary supplement ingredient is a new dietary ingredient, the expectation was that the guidance would be consistent with DSHEA. Unfortunately, the draft guidance serves to undermine DSHEA in a number of important respects.

For example, the draft guidance would require a manufacturer to submit an NDI notification for every dietary supplement containing an NDI. This is directly contrary to the language of DSHEA, which requires notification only of the intent to use an NDI. The FDA's misinterpretation of this provision is far from harmless. Indeed, this burdensome requirement would impose substantial, additional costs on manufacturers without providing additional safety benefits, and would undermine the access to safe, affordable dietary supplement products that DSHEA was designed to ensure. Similarly, the draft guidance attempts to assert that synthetic copies of botanicals can never be a dietary ingredient, an assertion that is wholly without statutory basis, and in fact contradicts longstanding FDA policy. The draft guidance also unduly limits the types of physical modifications that do not result in "chemically altering" a dietary ingredient by incorrectly construing the list in DSHEA legislative history as an exclusive rather than illustrative list. Furthermore, it diverges from our intent by including only ingredients that were marketed before enactment of DSHEA in the form of dietary supplements as "old dietary ingredients." The term dietary supplement wasn't even defined prior to DSHEA.

Because of these and other concerns, we urge FDA to immediately withdraw this guidance and start the process of crafting a new document that addresses these and other concerns. As part of that process, we would ask that you direct your staff to sit down with our staff early in January to discuss these concerns in more detail.

Thank you for your attention to this matter. We look forward to your prompt reply. If you have any questions, please have your staff contact Jenelle Krishnamoorthy with Senator Harkin and Hayden Rhudy with Senator Hatch.

Sincerely,

Tom Harkin
U.S. Senator

Orrin G. Hatch
U.S. Senator

Cc: Jeanne Ireland