United States Senate
WASHINGTON, DC 20510

June 21, 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:

We write to express our support for the upcoming publication of the new dietary ingredients (NDI) guidance and to clarify our expectation that it be consistent with the legislative compromise enshrined in the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Section 113(b) of the FDA Food Safety Modernization Act (P.L. 111-353) enacted on January 4, 2011, states that not later than 180 days after the date of enactment of this Act, the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient; when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act; the evidence needed to document the safety of new dietary ingredients; and the appropriate methods for establishing the identify of a new dietary ingredient.

The basic purpose of the NDI guidance is twofold. First, the purpose is to provide clarity, predictability, and certainty to dietary supplement manufacturers and the public on the Food and Drug Administration's (FDA's) interpretations and expectations related to the marketing of new dietary ingredients. In addition, the purpose is to effectuate the regulatory balance that Congress struck in writing DSHEA. In DSHEA, Congress made clear that consumers should continue to have access to dietary supplements that meet the law's definition, and were sold in the U.S. prior to the law's enactment. While the guidance should clarify when manufacturers must submit New Dietary Ingredient Notices, it should also refrain from erecting barriers that will inhibit or needlessly delay consumer access to safe products that were in fact marketed in the U.S. prior to October 15, 1994. The intent of the law was to give FDA the tools necessary to help ensure the safety of dietary supplements and the accuracy of the limited claims allowed for them, but also to minimize regulatory burdens that might inhibit consumer access to lawfully manufactured and labeled supplement products.

Once the guidance is published, we also encourage you to conduct outreach to educate manufacturers and consumers about the new NDI guidance and FDA's regulatory expectations in this area.

Thank you for your consideration.

Sincerely,

Tom Harkin
U.S. Senator

Orrin G. Hatch
U.S. Senator

Cc: Jeanne Ireland