

**Congress of the United States**  
**Washington, DC 20515**

February 09, 2012

The Honorable Margaret Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Building 1, Room 2217  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write to express our regret with the Food and Drug Administration's (FDA) dismissal of Senator Hatch and Senator Harkin's December 20, 2011 request to withdraw the draft guidance for Industry entitled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," which was published on July 5, 2011.

Congress included language in the Food Safety Modernization Act directing FDA to clarify when a dietary supplement ingredient is a new dietary supplement ingredient, intending that any FDA guidance would conform to the Dietary Supplement Health and Education Act (DSHEA) of 1994. However, the draft guidance released by FDA in July of 2011 appears to undermine DSHEA in a number of critical respects. Therefore, we respectfully request once again that FDA withdraw this guidance and begin work on a new draft that does not undermine the balance Congress struck in DSHEA to provide consumers with access to safe, affordable dietary supplement products.

DSHEA created a balanced system that provides consumers with access to safe dietary supplements and a legal framework that provides clarity to the industry regarding how products are to be regulated. Statutory language, as well as legislative history, clearly show that Congress did not intend to give FDA pre-market review of new dietary ingredients, nor did it intend to permit the agency to treat dietary ingredients in the same manner as food additives. Yet, the draft guidance released by FDA seems to run counter to the will of Congress by: erecting new extra-legal barriers to market entry of dietary supplements; imposing food additive type evaluative criteria; requiring multiple New Dietary Ingredient (NDI) notifications for dietary supplements beyond those required by law; and transforming the legal requirements for marketing of dietary supplements that contain NDIs from the notification process described under law to an FDA approval process.

We cannot find the statutory basis by which FDA has read these requirements into the law.

For example, DSHEA clearly stipulates that dietary ingredients sold in the United States before October 15, 1994, ten days prior to enactment of DSHEA, are deemed to be safe. Following the

enactment of DSHEA, the industry associations prepared lists of these “grandfathered” ingredients for FDA review. The draft guidance, however, explicitly rejects these lists and instead requires each manufacturer to shoulder the burden of maintaining records that show use of an ingredient prior to 1994 to classify an ingredient as “grandfathered.” If a particular manufacturer is unable to supply this data – a difficult burden some 17 years after the fact – the draft guidance would appear to allow FDA to re-characterize the old ingredient as a new one, subject to regulatory burdens associated with an NDI. Particularly for small companies that are new entrants to the industry since 1994, the burdens of procuring this historical data may be cost-prohibitive and unnecessary if other companies have already demonstrated the pre-1994 use of the ingredient.

FDA cannot now seek to undo by guidance a distinction that Congress so clearly secured in legislation.

In addition, the draft guidance appears to require each manufacturer of a finished dietary supplement to provide a separate NDI notification if the product contains an NDI. Since 1994, FDA has interpreted the NDI notification requirement to apply to the ingredient – not individual products – permitting ingredient suppliers to submit the notification and then allow their customers to use that ingredient in various formulations, within the ranges and serving amounts described in the original notification, without separate and duplicative filings. In fact, in developing the regulations for NDI submissions in 1997, FDA estimated the number of NDI notifications it expected each year to equal the number of new ingredients it anticipated in the market. Thus, for the draft guidance to assert that the NDI notification requirement applies to each finished product appears to run counter to the statute, the earlier rulemaking, and FDA’s longstanding practice. Such an interpretation would also result in duplicative filings and significant burdens on both the industry and the agency itself.

These are but two of the many aspects of the draft guidance that we believe must be addressed. If implemented as written, we believe that the draft guidance would overturn the rules that have been in place for the last 17 years and significantly increase the burden on the supplement industry far beyond the intent of Congress with no apparent benefit for consumers.

Again, we strongly urge FDA to withdraw this guidance and instead design a fair and workable NDI notification system. We also request that FDA refrain from taking any enforcement action that is based solely on positions articulated in the draft guidance that are not unequivocally grounded in the law. In the unfortunate event that FDA does not withdraw or reconsider this guidance as requested, legislation to clarify current statute will be considered.

Thank you for your attention to this matter. We look forward to your prompt reply.

Sincerely,



Jason Chaffetz (UT-03)  
Member of Congress



Dan Burton (IN-05)  
Member of Congress