Congress of the United States

Washington, DC 20515

October 22, 2009

Dr. Margaret Hamburg.
Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Commission Hamburg:

As the co-chairs of the Congressional Dietary Supplement Caucus, we are writing to express our concern regarding the Food and Drug Administration's (FDA) delay in implementing the Dietary Supplement Health and Education Act of 1994 (DSHEA). DSHEA was signed into law by President Clinton on October 25, 1994. DSHEA provides a clear pathway to market for prospective dietary ingredients (for use in dietary supplements) that have previously undergone extensive study for potential applications as pharmaceuticals.

One of the overreaching purposes in enacting DSHEA was to encourage the serious scientific study of ingredients intended for use in dietary supplements, while at the same time providing protection for the intellectual property of companies that identify new natural molecules with the potential to improve human health, and which are able to complete the new drug approval process. Provisions included in DSHEA to specifically prevent a company from taking a natural product to market is/was the subject of the FDA approval process, but those provisions also allow the company that holds the IND an alternative route to market as a dietary ingredient in a dietary supplement. Toward this end, DSHEA sets out a clear pathway: submission of the new ingredient for review, request for rulemaking and timely action by FDA. The fact that FDA has not acted to implement this portion of DSHEA has left companies that are compliant in limbo.

We continue to believe that it is in the best interest of the public health for the law and FDA policy to work hand-in-hand to encourage entrepreneurial investment in the identification and research of naturally occurring substances with the potential for approval as pharmaceutical ingredients. In order to do this, it is imperative that companies understand that there is a viable pathway to market their ingredients in the event that for reasons unrelated to safety, they are unable to complete the drug approval process. This pathway to the market was established by DSHEA and should be implemented. We would like to see this problem rectified in the near future.

We are troubled that the FDA may be using concerns related to the relationship that is part of Section 301 of the Federal Food and Cosmetic Act (FDCA), which prohibits the addition of "drugs" to food and also part of Section 201 relating to the use of prospective dietary ingredients that have been the subject of an IND, as a rationale for not moving forward on issues concerning the matter discussed above. The Food and Drug Administration Amendments Act of 2007 added this portion of Section 301 to the FDCA in 2007. Despite the absence of any indication that Congress intended for the new law to replace any existing law, on July 29, 2008, FDA announced that it was soliciting comments on whether Section 301 should apply to dietary supplements. The comment period on this issue closed in November 2008. DSHEA was enacted to ensure consumer access to well-researched products that will benefit public health; however, to date, FDA has failed to speak on the issue. We would like to see FDA resolve this issue promptly and begin to fully implement DSHEA in the coming year.

We believe that FDA should resolve these issues without further delay. We thank you in advance for you attention to this matter.

Sincerely,

Congressman Jason Chaffetz

Congressman Robert Wexler

Congressman Dan Burton

Congressman Jared Polis