

Please Sponsor HR 3380 in the Senate
To Help Protect Products from the FDA's Attempted End-Run Around DSHEA

Date: _____

Senator Orrin Hatch
104 Hart Senate Office Building
Washington, DC 20510

Senator Tom Harkin
731 Hart Senate Office Building
Washington, DC 20510

Dear Senators Hatch and Harkin:

Please sponsor H.R. 3380, the Dietary Supplement Protection Act of 2011 in the Senate to protect products from being declared unapproved new dietary ingredients NDI by the Food and Drug Administration by moving the grandfathering in date from 1994 to 2007. Your hard work brought about the Dietary Supplement Health and Education Act of 1994 (DSHEA), which affirmed the appropriate regulatory framework for dietary supplements as foods. A majority of Americans have voted with their wallets to show they desire to maximize the benefits of dietary supplementation for better health. The protection of the industry led to the creation of hundreds of new businesses and thousands of sustainable jobs.

Over the last 17 years since DSHEA has passed, it has been frustrating at times to see the FDA drag their feet at fully implementing the law, and to get it wrong so much of the time with issues such as health claims and now with the Draft Guidance Document for New Dietary Ingredients (NDI). While the industry asked for clarification of the 1997 NDI Regulation, the FDA is seeking to change the regulation via guidance document rather than to clarify. Such action calls for Congress to intercede and stop the FDA. One way of doing that is with H.R. 3380.

What the FDA is proposing with the NDI Guidance document will drive the cost of supplements up, making them less accessible, while costing many American jobs. The agency will stifle innovation especially in smaller companies who cannot meet the additional burdens of the new regulation masked as a guidance document. **H.R.3380 – the Dietary Supplement Protection Act of 2011 is an important bill. I hope that you will work together to introduce this bill in the Senate and to see it passed into law.**

As you know the FDA is attempting in this NDI Guidance to implement a more 'drug' like premarket approval process. I wholeheartedly disagree with their approach and want you to stop them. In 1994, you wisely included the following specific caveat to the agency, *"the [FDA] should not take any action to impose regulatory barriers limiting or slowing the flow of safe products..."* The FDA has ignored this caveat in crafting what is a fatally flawed NDI guidance document.

Please protect my access to supplements.

Sincerely,

Signature

Print Name

Address

City

State Zipcode+4