

December 12, 2016

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: FDA-2011-D-0376-1893, Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry

To Whom It May Concern:

The organizations signed below represent integrative health care practitioners throughout the United States. We write to express opposition to this draft guidance.

Safely formulated dietary supplements are an important part of the toolkit of integrative health care practitioners. They have a critical place in promoting health and preventing disease. Our members provide an essential role in guiding their patients toward the appropriate supplements selected from reputable, high-quality brands.

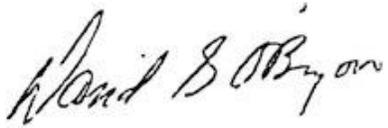
If the Food and Drug Administration's (FDA) draft guidance as written were to be implemented, considerable complexity and cost would be added to routine dietary ingredient manufacturing processes. The outcome would inhibit patient access to these safe and effective interventions.

It is unclear why the far-reaching reinterpretation of the Dietary Supplement Health and Education Act (DSHEA) presented in the FDA draft guidance is necessary and what problem it seeks to solve. According to DSHEA, it is only incumbent on manufacturers or distributors to submit a notification of the intent to use a New Dietary Ingredient (NDI), and to provide the information that is the basis for the submitting company's conclusion that a dietary supplement containing the NDI is reasonably expected to be safe.

We do know that this draft guidance would interfere with the care received by the millions of patients served by our members. Our organizations respectfully request the FDA draft be withdrawn and that the FDA instead enforce the NDI provisions of DSHEA as established by Congress, ensuring that consumers retain access to safe and affordable dietary supplements.

Thank you very much for your consideration. If you have any questions, please contact Michael Jawer of the American Association of Naturopathic Physicians ([mike.jawer@naturopathic.org](mailto:mike.jawer@naturopathic.org); 202-237-8150).

Sincerely,



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