

# FDA – The NDI Guidance Docket Will Kill US Jobs & Regulate the Innovators in the Dietary Supplement Industry Out of Existence

To: DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm.1061  
Rockville, MD 20852

Date \_\_\_\_\_, 2011

**Re: Docket No. FDA-2011-D-0376, Draft Guidance for Industry;  
“Dietary Supplements: New Dietary Ingredient Notifications and  
Related Issues.”**

## The Current NDI Guidance Document Misses the Mark and Needs to Be Completely Withdrawn/ Rewritten

1. **The FDA’s interpretation of what is a New Dietary Ingredient (NDI) is much broader than what the Dietary Supplement Health and Education Act of 1994 (DSHEA) intended** and, if adopted, this Guidance document could cause the loss of over 200,000 jobs and result in a total economic loss to the U.S. economy of more than \$30 billion annually, according to Dr. Shepherd-Bailey, Ph.D., of Emory University School of Law.
2. **The Draft Guidance goes against Congress’s specific intent** in the 1994 Dietary Supplement Act (DSHEA) that: *“the [FDA] should not take any actions to impose regulatory barriers limiting or slowing the flow of safe products ... to consumers”*. Yet the proposed Draft Guidance imposes onerous reporting, safety testing and evidentiary burdens, and even in some cases animal and human studies, on manufacturers that go way beyond the current industry standards. If finalized, this guidance will force thousands of supplement manufacturers out of business.
3. **The Draft Guidance goes against Congress’s specific intent** in DSHEA that: *“dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare;”* Yet this guidance would give the overarching presumption that dietary supplements and new dietary ingredients (NDIs) are inherently dangerous and extensive safety and compliance measures must be required.
4. **Despite DSHEA’s clearly stated law** that: *“dietary supplements shall be deemed food”* and despite U.S. Senate findings that: *“nearly all consumers indicate that dietary supplements should not be regulated as drugs,”* the proposed evidentiary requirements essentially treat food supplements and ingredients like toxic drugs, as if they are presumed dangerous, when really any NDI, even if not marketed before 1994, **is still a food**: an herb, an amino acid, a vitamin, a mineral, or other ingredient defined in DSHEA.
5. **And most importantly**, this guidance if adopted, would cause the loss to consumers of their most treasured asset ... **their health!**

**Don’t let dietary supplements be regulated out of existence!** Withdraw the NDI Draft Guidance immediately so that I may access the dietary supplements and NDIs on which I and millions of Americans’ thrive!

### Additional Comments:

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Name [Signature]

Name [Print]

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Address

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