



Alliance for Natural Health USA  
1350 Connecticut Ave NW  
5th Floor  
Washington DC 20036

email: [office@anh-usa.org](mailto:office@anh-usa.org)  
tel: 800.230.2762  
fax: 202.315.5837  
[www.anh-usa.org](http://www.anh-usa.org)

ANH-USA is a regional office of ANH-Intl  
**INTERNATIONAL**  
[anhinternational.org](http://anhinternational.org)

## Press Release

### FOR IMMEDIATE RELEASE

Contact: Darrell Rogers  
202.467.1986  
email: [darrell@anh-usa.org](mailto:darrell@anh-usa.org)

# Proposed FDA Dietary Supplement Guidelines Needlessly Hurt Innovation and US Economy

*FDA severely underestimates damage caused to natural  
products industry by proposed guidelines*

**August 3, 2010 (Washington, DC)** — Last month the FDA released draft industry guidance on the New Dietary Ingredient (NDI) notification process (Guidance) for natural products companies. In its request for comments, the FDA estimates that the burden associated with its Guidance “will be minimal.” The Alliance for Natural Health USA (ANH-USA), represented by Emord & Associates, filed official comments, stating, “The FDA’s estimate of the burden of the proposed requirement is inaccurate and has grossly and irresponsibly underestimated the economic impact of its Guidance.”

“The FDA’s assessment couldn’t be further from reality,” said Gretchen DuBeau, executive director of ANH-USA. “We have spoken with the natural products industry and had an expert on federal regulations research the Guidance. Our research tells us we can expect a major disruption in the dietary supplement market, forcing products off the shelves. This will result in billions of dollars in losses, reduced consumer access, and unemployment of 100,000 Americans,” said DuBeau.

**“Promoting sustainable health and freedom of choice in healthcare through good science and good law”**

ANH-USA's comments to the FDA say that "FDA's estimate of the amount of paperwork required, number of man-hours required to satisfy Guidance criteria, and the overall impact are grossly below those predicted by regulations expert and Emory University Professor of Law and Economics Joanna Shepherd Bailey." Rather than the fifty-five NDI notification submissions which FDA predicts, Dr. Shepherd Bailey expects between 22,240 and 125,000 submissions, at a total cost to the industry to be between \$845 million and \$6.1 billion.

ANH-USA has written extensively on the Guidance and has found that ingredients which have been in supplements and in the food supply for decades may be subject to the NDI process. As a result, consumers will have fewer dietary supplement options and will pay higher prices for the products that remain for sale. Losses will be especially devastating in the current economic climate.

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**About the Alliance for Natural Health USA (ANH-USA)**

[www.anh-usa.org](http://www.anh-usa.org)

The Alliance for Natural Health USA is part of an international organization dedicated to promoting natural, sustainable healthcare through good science and good law. We protect the right of natural health practitioners to practice, and the right of consumers to choose the healthcare options and treatment modalities they prefer, including complementary and alternative medicine. As a membership-based organization, we unite consumers, practitioners, and industry to speak with a common voice and have worked since 1992 to shift the medical paradigm from an exclusive focus on surgery, drugs and other conventional techniques to an "integrative" approach incorporating food, dietary supplements and lifestyle changes.