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Natural Health Group Claims FDA is Defying Federal Law

Group ask the agency to withdraw its draft guidance for the dietary supplement industry; hundreds of thousands of messages sent and 20,000 phone calls made to FDA and Congress

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December 5, 2011—Calling the US Food and Drug Administration's actions "outrageous," the Alliance for Natural Health USA (ANH-USA) says that FDA's new guidelines could create economic losses of up to $10 billion, and cause a majority of nutritional supplements to be withdrawn from the market.

The organization also claims that FDA's "Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" violates both the intent and the letter of the laws governing supplements as well as the Administrative Procedure Act (APA).

"The New Dietary Ingredient (NDI) Draft Guidance is in fact an egregious new set of rules that depart from FDA's previous standards, alter the rights of supplement manufacturers, and will greatly reduce consumers' access to nutritional supplements! The NDI document is binding on industry, and FDA must scrap it completely or else the agency will stand in violation of federal law," stated Gretchen DuBeau, executive and legal director of ANH-USA.

In formal comments submitted to the FDA, drafted by acclaimed attorney Jonathan Emord on behalf of ANH-USA, the organization claims FDA is engaged in substantive new rulemaking. "The APA says if an agency's action is legislative in nature, that's rulemaking," explained Emord. "The Guidance distorts the plain language of the laws that govern supplements. FDA needs to comply with the APA's formal rulemaking requirements, not issue unilateral guidance as a deceptive means of creating new rules."

This summer, in collaboration with ANH-USA, Joanna M. Shepherd Bailey, PhD, professor of law and economics at Emory University, demonstrated the burdens both the supplement industry and consumers would face if FDA enforces its NDI Draft Guidance. Her report found that:

- Between 22,240 and 41,700 nutritional supplements would likely be removed from the market, at an economic loss of between $5.6 billion and $10.5 billion;
- The nutritional supplement market could shrink by between 28% and 52.5%, producing an annual loss for the industry of between $7.84 billion to $14.7 billion; and
- Between 55,720 and 104,475 jobs in the supplement industry could be lost.

In addition to dodging APA rulemaking procedure and causing an economic disaster, the FDA is, according to ANH-USA, demonstrating its clear bias against nutritional supplements. "FDA had a chance to show the supplement community that the agency learned from its previous mistakes, but unfortunately it only confirmed the public's distrust," said DuBeau.

ANH-USA contends that the NDI notification system was intended to ensure safety—and the very reason pre-DSHEA supplements were grandfathered in is because they had proven themselves safe through years of use by hundreds of thousands of consumers. "If safety is of utmost concern to FDA, why does the Guidance document burden the supplement industry with regulatory requirements that have nothing to do with proving the safety of the supplements? It appears FDA is acting out of spite—and in not the public's best interest," DuBeau stated.

"We believe FDA will be unable to incorporate enough changes to their Draft Guidance to bring it in line with the letter of the law, preserve supplement access for customers, and remove needless regulatory hurdles for industry. Accordingly, we have requested FDA withdraw the Draft Guidance at the earliest possible moment," DuBeau concluded.

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About the Alliance for Natural Health USA (ANH-USA) ▪ http://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.