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Consumer Advocacy and Trade Groups Meet with FDA on New Supplement Guidance

*Agency bows to congressional pressure and begins a rewrite
after massive grassroots letter-writing campaign*

August 1, 2012 — The Alliance for Natural Health USA (ANH-USA), together with a number of supplement industry trade associations, met yesterday with the US Food and Drug Administration to discuss a wholesale revision of the FDA's draft guidance for New Dietary Ingredients (NDIs).

The guidance was originally released in July of 2011, and was soundly criticized by consumers, natural health advocates, industry, and Congress. The Dietary Supplement Health and Education Act of 1994 (DSHEA) required manufacturers to notify the FDA when they brought new dietary ingredients and nutritional supplements onto the market—but left the specific guidelines on how it would be implemented up to FDA.

“FDA's draft guidance, issued seventeen years after the DSHEA's passage, was supposed to clarify how this notification process was to take place,” said Gretchen DuBeau, executive and legal director of ANH-USA. “Unfortunately, FDA turned it into a de facto pre-market approval system with so many absurd restrictions and arbitrary rules that it would have caused major disruptions in the dietary supplement industry, forcing significant numbers of products off the market, losing over \$1 billion in revenue, and costing over 100,000 Americans their jobs.”

In June, after a massive grassroots letter-writing campaign, congressional leaders persuaded FDA to withdraw the guidance and start over—a startling reversal from the agency's previous

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

intransigence on the subject. Monday’s meeting between FDA, industry, and natural health and consumer activists was called “significant” and “constructive.”

“The meeting went well,” DuBeau said. “It was the first time consumers were able to be at the table. We discussed a range of issues, including how the FDA will determine which ingredients are grandfathered—and thus not subject to the NDI notification process. We are cautiously optimistic that FDA heard our concerns and those of the supplement industry. However, this is a complicated process; it’s likely there will be a series of meetings over a long period of time. We will continue to work closely with the agency as things develop.”

The meeting’s participants were able to identify some specific areas for FDA to work on immediately, such as how manufacturers should properly identify their ingredients in NDI notifications. “A majority of NDI notifications are rejected because of these simple errors, and they could be corrected very easily with the proper guidance,” noted DuBeau.

“ANH-USA was the only grassroots advocacy consumer group at the table. All the rest were trade associations. We believe it was our strategy of working with Congress—and in particular, with the appropriations committee that controls FDA’s purse strings—that brought FDA to the table,” DuBeau said. “Now that FDA is finally listening to the people for whom the guidance was written, we will keep a close watch on the rewriting process, monitoring it to make sure the interests of consumers are honored: protecting their access to a broad choice of nutritional supplements.”

A recent study sponsored by the CDC’s National Center for Health Statistics found that 165 million Americans (about 53 percent of the population) take some sort of dietary supplement on a daily basis.

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

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.