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

email: office@anh-usa.org
tel: 800.230.2762
fax: 202.315.5837
www.anh-usa.org

ANH-USA is a regional office of ANH-Intl
INTERNATIONAL
anhinternational.org

PRESS RELEASE

FOR IMMEDIATE RELEASE

Contact: Darrell Rogers
202.255.0527
email: drogers@anh-usa.org

Proposed FDA Dietary Supplement Guidelines Modeled after Restrictive European Regime

FDA attempt to freeze-frame the US natural products sounds the death knell for innovation and access

July 28, 2010 (Washington, DC) — Earlier this month, the US Food and Drug Administration dropped a bomb on the natural supplement community. The FDA released draft industry guidance on the New Dietary Ingredient (NDI) provision in the Dietary Supplement Health and Education Act of 1994 (DSHEA).

“Unfortunately, the FDA draft guidelines—released seventeen years late—are a perversion of Congress’s original intent,” said Gretchen DuBeau, Executive Director of the Alliance for Natural Health USA. “The NDI notification system that DSHEA outlined was supposed to be about notification, plain and simple. But with this new guidance, the FDA has in effect created a pre-approval system—with the FDA itself as the ultimate arbiter of what dietary supplements will and will not be available."

“Our colleagues in Europe studied the proposed FDA system,” DuBeau continued, “and realized that it is modeled after a EU regulatory framework that has done much damage to the natural health community there.”

Robert Verkerk, Scientific Director of ANH-USA and Executive and Scientific Director of ANH-Europe, agreed. “In Europe, regulators use the Novel Foods Regulation to force products off the market. The FDA draft guidance is eerily similarly to European regulations,” he said. “This should serve as a wake-up call to practitioners and citizens who rely on diverse natural ingredients for their healthcare. The NDI draft guidance is an unabashed attempt to clone one of the most lethal tools presently being used in the EU to decimate Europe’s natural products industry.”

ANH-USA has written extensively on the NDI draft guidance and has found that the draft guidance considers many ingredients currently on the market NDIs—in fact, any product formulated after 1994—would be subject to a complicated, burdensome, and costly notification process, essentially making it a pre-approval process. Ingredients that have been in supplements and the food supply for decades but which have been chemically altered in any way are also subject to NDI notification process. Moreover, the FDA definition of “chemically altered” is extremely broad, describing numerous commonly used manufacturing processes.

“Because the Alliance for Natural Health International has offices in Europe and the United States, we are keenly aware of regulatory trends affecting natural health access worldwide. This international perspective provides the natural health community unique insight into the threats we face, and provides effective methods for political activism,” DuBeau concluded.

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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.