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Press Release

FOR IMMEDIATE RELEASE

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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 FDA dropped a bomb on the dietary 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 17 years late - are a perversion of the intent of Congress, The NDI notification system that DSHEA outlined was supposed to be about notification, plain and simple. Our colleagues in Europe studied the proposed FDA system and see that it is modeled after a EU regulatory framework that has done much damage to the natural health community there," said Gretchen DuBeau, Executive Director of the Alliance for Natural Health USA. "By turning what was meant to be a pre-market notification system into what in practice has become a pre-approval system, the FDA has made themselves the ultimate arbiter of what dietary supplements will and will not be available," said DuBeau.

"In Europe, regulators use the Novel Foods Regulation to force products off the market. The FDA draft guidance is eerily similarly to European regulations and should serve as wake up call to practitioners and citizens who rely on diverse natural ingredients for healthcare," said Robert Verkerk ANH-USA Scientific Director and ANH-Europe Executive and Scientific Director. "The NDI draft guidance is an unashamed attempt to blueprint one of the most lethal weapons presently being used in Europe to decimate its natural products industry," said Verkerk.

ANH-USA has written extensively on the NDI draft guidance and has found that the draft guidance considers many ingredients currently on the market NDIs, and subject to the complicated, burdensome and costly notification process. Ingredients that have been in supplements and the food supply for decades that have been chemically altered in any way are subject to NDI notification process. Moreover, the FDA definition of "chemically altered" is extremely broad, describing multiple 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 effective methods for political activism," said DuBeau.

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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.