

## **FDA Sets up Meeting to Discuss New Dietary Ingredients (NDIs)**

The Food and Drug Administration (FDA) is holding a public meeting on 15 November to give industry and consumers the chance to discuss the government body's pre market notification program for new dietary ingredients (NDIs).

The FDA is also inviting the supplement industry and the public to submit written comments by December 3, 2004 on the subject. In a statement on its website <<http://www.fda.gov/ohrms/dockets/98fr/04n-0454.nm00001-vol1.pdf>>, the organization explained that the purpose of the meeting was to clarify the section of DSHEA that deals with NDIs. It noted that this action had been prompted by the receipt of a "number of omissions and other problems" in notifications sent in by various players to comply with the NDI legislation.

More specifically the FDA said that certain companies had failed to "adequately describe the identity and composition of the NDI", to provide enough information proving that the substance was an NDI or to put forward comprehensive safety information.

The FDA stated that it hopes the November meeting will reveal how it can aid the industry to respond better to the requirements of DSHEA.

The American Herbal Products Association (AHPA) - cited in the statement to substantiate the FDA's observation that the supplement industry recognized the need for the government body to clarify the statutory requirement for NDI notifications gave a cautious welcome to the announcement of the meeting.

"All AHPA members should be encouraged that the agency has called for a dialogue on the federal NDI program, but should also pay attention to the detailed language in FDA's notice," said Michael McGuffin, president of the association, adding that the AHPA will attend and provide oral presentations at the meeting.

Toby Young, the AHPA's general counsel, noted, moreover, that congress included the NDI section of DSHEA "to clearly place upon industry the responsibility for demonstrating that new ingredients are reasonably expected to be safe for their intended use, and the industry and its trade associations must now be fully engaged in this regulatory process."

In order to focus attentions, the FDA has included in its statement a list of questions concerning the legislation, focusing particularly on the safety concerns that could apply to NDIs.

The November 15, 2004 meeting is scheduled from 9am to 5pm at FDA's offices in College Park, MD. Pre-registration may be made until November 10 to Kelly Williams-Randolph ([Kelly.Williams@cfsan.fda.gov](mailto:Kelly.Williams@cfsan.fda.gov)).