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NDI DRAFT GUIDANCE COMMENTS

ANH-USA: 'Unworkable and irrational' NDI guidance is rulemaking by the backdoor

By Elaine Watson, 06-Dec-2011

Related topics: Regulation, NDI draft guidance

Health advocacy group the Alliance for Natural Health USA (ANH-USA) is exploring all available "*legal remedies*" should the Food and Drug Administration (FDA) fail to ditch or substantially revise its draft guidance on new dietary ingredients (NDIs).

The draft guidance - published in July - was supposed to clarify the NDI process, said food law attorney Jonathan Emord, who penned comments to the FDA on behalf of the ANH-USA.

Instead, the FDA had engaged in "*substantive new rulemaking"* by the backdoor by imposing *"new and excessive burdens that have no rational relationship to the statutory purpose of the NDI provision",* he argued.

It had also put supplement makers in an intolerable position by rendering scores of supplements already on the market technically unlawful, claimed Emord, who urged the FDA to ditch the offending document immediately.

Ditch guidance now – or firms are left in legal limbo

He added: "*Companies that fail to comply with the specific provisions of the NDI guidance clearly market adulterated products. The binding nature of the NDI guidance is thus apparent.*

"The FDA should comply with the requirements of the Administrative Procedure Act by relying on formal rulemaking rather than on unilateral issuance of a guidance to declare new rules."

FDA is violating federal law with 'arbitrary and capricious' action

ANH-USA executive and legal director Gretchen DuBeau added: "*FDA must scrap it completely or else the agency will stand in violation of federal law*."

Asked by NutraIngredients-USA what legal avenues were being explored should the FDA refuse to listen, a spokesman added*: "We can't speak to the specifics just yet*, [but] *we are exploring legislative and legal remedies if FDA is unable to follow the intent and letter of the Dietary Supplement Health and Education Act (DSHEA)*."

While the ANH-USA accepted guidance was "*required by DSHEA*", he added, it was not the FDA's job to "*promulgate new NDI rules through guidance rather than the proper rule-making procedure.*

"By starting with a clean sheet of paper, and receiving input from the supplement community, it is possible that FDA can provide guidance for a notification system for NDIs that does not threaten consumer access."

Unworkable and irrational?

Getting down to specifics, the ANH-USA takes issue with:

- The amount and nature of **the evidence the FDA requires firms to submit in order to establish a reasonable expectation of safety**: "*The FDA has required that manufacturers produce the same data in a 75-day notification as would be required in a GRAS submission. This is in direct conflict with the legislative history of DSHEA."*
- The insistence on multiple **end-product specific notifications**: "*FDA cannot show anything in the statute that supports the notion that separate NDI notifications are required by each company....The FDA has enacted an*

unworkable and inherently irrational scheme lacking objective enforcement standards."

- The refusal to accept industry lists of '**grandfathered' old dietary ingredients**: "*Contrary to the FDA's position, the plain meaning of Section 350b(c)* [of the Food, Drug, and Cosmetic Act] *that a dietary ingredient sold in the food supply before October 1994, whether as an ingredient in food or in dietary supplements, is grandfathered and excluded from the NDI provisions in Section 350b."*

- The argument that **new extraction technologies** should trigger an NDI notification: "*In short, only the most basic manufacturing methods would not chemically alter an ingredient (dehydration, lyophilization, milling). The result is to deny use of innovations that leave the biochemistry of ingredients unchanged but that involve new modalities for production."*
- The claim that **synthetic botanical constituents** are not dietary ingredients, even if they are chemically identical to their 'natural' counterparts: "*The FDA has provided no reasoned basis to conclude that synthetic botanicals present a heightened safety risk."*

- FDA's interpretation of '**history of safe use'** (25 years of widespread safe use'): "*FDA has no factual basis to conclude that a dietary supplement marketed safely for 25 years has exhibited sufficient safety when an identical product marketed for 24 years has not.* [The definition is] "*arbitrary, capricious, and inconsistent with the statutory language."*