

**Before the  
U.S. Food and Drug Administration  
Washington, D.C.**

***In re* Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability, 76 Fed. Reg. 39111 (July 5, 2011)**

**Docket No. FDA-2011-D-0376**

**COMMENTS OF  
ALLIANCE FOR NATURAL HEALTH – USA**

Alliance for Natural Health – USA (ANH), by counsel and in response to the FDA's request for comments in the above-referenced docket, hereby submits this detailed assessment of the agency's draft Guidance document: "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," published July 5, 2011. In the guidance, FDA provides its interpretation of 21 U.S.C. § 321(ff), 21 U.S.C. § 350b, and 21 C.F.R. § 190.6 concerning "new dietary ingredients" (hereinafter "NDI"). (1) The NDI guidance is in fact a new rule and, as such, is adopted in violation of the Administrative Procedure Act provisions requiring notice and comment rulemaking. (2) The NDI guidance is an ultra vires administrative action because it exceeds the plain and intended meaning of the NDI provisions of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 350b. (3) The NDI guidance is arbitrary and capricious agency action, and an abuse of discretion, because it interprets the NDI provisions of the Act in ways contrary to the plain language and intended meaning of the statute, imposing new and excessive burdens that have no rational relationship to the statutory purpose of the NDI provision and causing the NDI provisions to conflict with the statutory meaning of other DSHEA provisions. (4) The NDI



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**Background of the Commenter**

The Alliance for Natural Health – USA (“ANH”) is a United States division of an international, not-for-profit, non-governmental organization with headquarters in Washington, D.C. ANH is the successor to the American Association for Health Freedom, which, in turn, is the successor to the American Preventive Medical Association founded in 1992. ANH's mission objectives include the promotion of natural health and consumer access to dietary supplements. ANH has a membership of over 177,000 activists, practitioners, medical doctors, scientists, business entities, consumers, and patients who variously manufacture, sell, distribute, recommend, and consume dietary supplements. ANH represents individuals and entities within the dietary supplement industry that are adversely affected by the FDA’s NDI Guidance. Its























































































dietary supplement industry billions of dollars in revenues and will increase unemployment by over 100,000 Americans. For the reasons explained in detail above, the FDA NDI Guidance exceeds the limits of the agency's statutory authority; the NDI Guidance contradicts the plain and intended meaning of the NDI statutory provision; and the NDI Guidance is arbitrary and capricious and abuse of agency discretion. ANH-USA therefore urges the FDA to withdraw the NDI Guidance at the earliest possible moment.

Sincerely,

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Dated: December 1, 2011