



Alliance for Natural Health USA
1350 Connecticut Ave NW
5th Floor
Washington DC 20036
email: office@anh-usa.org
tel: 800.930.9762
fax: 202.315.5837
www.anh-usa.org

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

Press Release

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Contact: Gretchen DuBeau
202.467.1988
email: gretchen@anh-usa.org

Arbitrary New FDA Rules Set to Put Dietary Supplement Manufacturers Out of Business

Alliance for Natural Health Sues FDA

Today the Alliance for Natural Health USA (ANH USA), along with dietary supplement formulators Durk Pearson and Sandy Shaw, and the Coalition to End FDA and FTC Censorship, filed suit in the U.S. District Court for the District of Columbia against the Food and Drug Administration (FDA). The suit seeks declaratory and injunctive relief on the grounds that FDA violated the Administrative Procedure Act's prohibition on arbitrary and capricious action when it adopted a rule that subjects dietary supplement manufacturers to the same criminal penalties for minor paperwork violations as for selling contaminated product.

ANH USA is a membership-based organization that protects the rights of practitioners and consumers of alternative medicine. ANH USA's professional and industry members suffer the most from the financial burdens imposed by the FDA rule, known as the Good Manufacturing Practice (GMP) regulations. This ruling declares that when a company fails to keep adequate records, a product is automatically deemed to be adulterated without requiring the FDA to prove that the product itself presents a risk of illness or injury. The rule conflicts with the Dietary Supplement and Education Act, which requires a risk of harm before a product can be declared adulterated and removed from the market.

According to ANH USA, the rule results in significant financial burdens on supplement manufacturers, some of whom may not be able to absorb the cost. FDA admits that the rule's implementation would eliminate 12 percent of the dietary supplement market.

Regarding the suit, ANH USA Executive Director Gretchen DuBeau said, "The FDA cannot be allowed to implement such a blatant attack on the dietary supplement industry, an industry millions of consumers depend on for valuable, affordable access to vitamins necessary to sustain health." FDA estimates that enforcement of the GMPs will reduce the variety of dietary supplements on the market and increase the cost of dietary supplements.

"Promoting sustainable health and freedom of choice in healthcare through good science and good law"

DuBeau continued, “We take this action today to stop the FDA, which is becoming nothing more than a tool used by Big Pharma to cut off consumer access to natural substances, from continuing its campaign against natural health.”

ANH USA is represented in this matter by Emord & Associates, P.C.

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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.