

Press Release  
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## US FDA Guidance on health claims signals possible end-run of DSHEA

**The American Association for Health Freedom (AAHF) in association with its international affiliate, the Alliance for Natural Health (ANH) have today submitted a powerful critique of the US Food & Drug Administration's (FDA) proposal for evaluation of health claims which has been open to public consultation.**

Since the passage of the Dietary Supplement Health & Education Act in 1994, American citizens have enjoyed one of the most liberal regimes for dietary supplements anywhere in the world. This legal regime was won only after unprecedented public lobbying of Congress, stimulated by concerns over unnecessary restrictions on natural products.

The FDA was forced to re-consider its approach to health claims following a Court of Appeals decision which followed the *Pearson v Shalala* case in 1999. The AAHF acted as joint plaintiffs in this ground-breaking case which challenged the FDA's decision to disallow four substance/disease relationship claims. However, this latest proposal by the FDA is set to create a situation where only the largest, most well funded companies, such as pharmaceutical corporations, will be able to afford the evidence-based, stringent data requirements for health claims. These requirements would prevent smaller companies, which have historically been the key pioneers and innovators in the natural health field, from making claims as they would not be able to afford the cost of substantiation.

Dr Robert Verkerk, Scientific Advisor to AAHF and Executive and Scientific Director of the ANH, who was the lead author of the AAHF's critique of the FDA Guidance, said:

*"The FDA is in danger of being swayed by processes in Europe which, if followed into law in the US, could have catastrophic effects on the US natural health industry. Consumers need adequate information which tells them which substances are beneficial in reducing the risk of particular diseases to help them make informed choices, but the FDA seems to want to raise the bar so high that much of this vital, health-giving information will be lost from product labels and supporting material. If smaller manufacturers are forced to omit information even if it is supported by scientific and clinical evidence, there is no doubt that this would be a fundamental infringement on our human right to freedom of information and choice".*

The FDA's proposed system which is almost exclusively reliant on evidence from human trials and observational studies, would likely ditch claims which were based on *in vitro* and biochemical studies, as well as animal studies, which are cheaper and have formed the basis of many structure/function claims to-date.

The AAHF and ANH are deeply concerned that the tone of the FDA Guidance document suggests a move by the FDA towards classic orthodox medicinal models, which will dispense of the framework that has led so many Americans towards taking responsibility for their own health.

**ENDS.**

## CONTACTS

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## EDITOR'S NOTES

### **Food & Drug Administration (FDA)**

FDA Guidance document is entitled "Guidance for Industry: Evidence-Based Review System for the Evaluation of Health Claims"

See full Guidance document at: <http://www.cfsan.fda.gov/~dms/hclmqui5.html>

### **Alliance for Natural Health (ANH)**

The ANH is a UK-based, internationally-active, non-governmental organization working to positively shape regulatory and scientific frameworks affecting natural health. As an alliance, the ANH brings together scientists, medical doctors, integrative practitioners, lawyers and consumers, as well as suppliers of food and dietary supplements, globally as a means of working towards the development of sustainable approaches to healthcare. The ANH has been extensively involved in inputs to European Member State governments, the European Commission and the European Food Safety Authority (EFSA) with regard to the EU Nutrition & Health Claims Regulation which came into force across Europe on 1 July 2007.

[www.anhcampaign.org](http://www.anhcampaign.org)

### **American Association for Health Freedom (AAHF)**

The American Association for Health Freedom (AAHF) is a 501©4 nonprofit organization serving as the politically active voice at federal and state levels to protect Americans' rights to access integrative medicine and dietary supplements. AAHF protects the right of the consumer to choose and the practitioner to practice by

lobbying Congress and state legislature and crafting legislation; acting as a government watchdog and filing comments on proposed rulings; educating the public, press, and decision-makers on integrative medicine; initiating legal activities and joining and forming significant coalitions.

[www.healthfreedom.net](http://www.healthfreedom.net)

**NOTE:**

The full critique by the AAHF/ANH can be downloaded at:

[http://www.alliance-natural-health.org/docs/ANHwebsiteDoc\\_278.pdf](http://www.alliance-natural-health.org/docs/ANHwebsiteDoc_278.pdf)