



PRESS RELEASE: For Immediate Release
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Natural health interests voice concern about possible new oversight by FDA on health claims

The American Association for Health Freedom (AAHF), and its European affiliate, the Alliance for Natural Health (ANH), today submitted written comments to the US Food & Drug Administration (FDA) in its current consultation on functional foods. As leaders in the health freedom community, AAHF and the ANH recommend better definitions or adapting existing regulations on functional foods and not creating new regulations that could ultimately reduce consumer choice or information.

AAHF and the ANH argue that if additional oversight is to be considered, it must be proportionate, as there is a very real risk that if excessively onerous provisions are required to “authorize” health claims, many of the smaller companies, which have typically been the pioneers in this field, will be prevented from including health claims of any type on their products. These smaller companies would be at risk of losing valuable market share to multinational companies that can afford to pay their way into the new regulatory regime while potentially selling inferior products.

Instead, AAHF/ANH urges the FDA to contemplate a process that balances consumer choice and safety issues with compliance issues for companies. Brenna Hill, AAHF Executive Director said, *“The FDA should not over-burden the industry or penalize educated consumers who are looking at reducing their risks from chronic diseases like heart disease and diabetes. Consumers have an exponentially greater interest in taking responsibility for their own health.”* In fact, AAHF/ANH point out that functional foods have been in the marketplace since the 1960s and have been consumed safely for decades. Since several of the top 10 diseases in the US have been shown to be associated one way or another with diet it is imperative to make sure that consumers are both properly informed and that adequate food choices are available to them.

As Scientific Director of AAHF and Executive Director of ANH, Robert Verkerk PhD, said, *“The tight regulation of health claims has been prioritized in Europe and a new regulation is about to be imposed, affecting Europe’s 450 million strong population. The regulation is in our view far too stringent, requiring a very high level of scientific substantiation including human clinical trials that would not be out of place in the field of drugs licensing.”* AAHF and the ANH agree that it might be fine for the largest corporations in the functional food arena, but it’s impractical for the smaller companies which have generally produced the most advanced and innovative products. Verkerk adds, *“We think it’s essential that the FDA doesn’t follow Europe on this issue, nor should it follow the developing international Codex guidelines, which are presently strongly paralleling European legislation.”*

Michael Ruggio, AAHF general counsel added, *“Legally, the situation is complex, especially as it looks like the FDA might unwittingly create increasing legal uncertainty in this area. The sorts of provisions that the FDA appears to be contemplating in their bid for increasing oversight on health claims is likely to significantly narrow the gap between the legal requirements for getting foods and drugs onto the market. Consumers could be the big losers here, unless we see a very well thought out approach which doesn’t disadvantage the smaller players in the industry.”*

As the AAHF/ANH representative, Ruggio made an oral presentation to the FDA on its functional food debate on December 5, 2006 and made clear the coalition’s concerns, as well as pointing out a possible way forward. This way forward is elaborated in the AAHF/ANH’s written response, which can be downloaded now from the ANH website (see link under ‘FDA consultation’ in Editor’s Notes below) and will be available on the AAHF website on Monday, January 8th at www.healthfreedom.net.

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EDITOR'S NOTES

FDA CONSULTATION

Summary of AAHF/ANH oral submission (made to the FDA by 5 December 2006):

<http://www.fda.gov/ohrms/dockets/dockets/02p0122/02p-0122-ts00009-02.pdf>

To view all submissions:

<http://www.fda.gov/ohrms/dockets/dockets/02p0122/02p0122.htm>

To view the full AAHF/ANH written consultation, go to the following link:

http://www.alliance-natural-health.org/docs/ANHwebsiteDoc_264.pdf

ABOUT THE AAHF AND THE ANH

The American Association for Health Freedom (AAHF) - www.healthfreedom.net

AAHF is the politically active voice at the federal and state level for the right of the consumer to choose and the practitioner to practice. We ensure health freedom by lobbying Congress and state legislatures 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 (e.g., lawsuits, amicus briefs, petitions), and joining and forming significant coalitions.

AAHF was founded in 1992 in direct response to the problems faced by practitioners and consumers in the United States. Medical freedoms were and continue to be threatened by the government agencies, the allopathic medical community, insurance companies, and state medical boards around the country. It is clear that health freedom need a strong advocate on Capitol Hill, in the state legislatures, in the courts, and with the media. AAHF is that health freedom champion.

The Alliance for Natural Health (ANH) - www.anhcampaign.org

The ANH is a UK-based, EU-focused, international, legal-scientific, non-governmental organisation that is working on behalf of consumers, medical doctors, complementary health practitioners and food manufacturers and distributors, to protect and promote natural healthcare, using the principles of good science and good law.

The ANH's principal objective is to help develop an appropriate legal-scientific framework and environment for the development of sustainable approaches to healthcare. Within this setting, consumers and health professionals should be able to make informed choices about a wide range of health options, and in particular those that relate to diet, lifestyle and non-drug-based or natural therapies, so that they may experience their benefits to the full while not exposing themselves to unnecessary risks.