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**FDA Public Meeting on Dietary Supplements
July 20, 1999**

**To assist FDA's Center for Food Safety and Applied Nutrition to
develop an overall strategy for achieving effective regulation of dietary
supplements under the Dietary Supplement Health and Education Act**

**Statement of the American Herbal Products Association
By Michael McGuffin
Chair, AHPA Government Relations Committee**

Good afternoon, and thank you for the opportunity to participate in this forum. The American Herbal Products Association, or AHPA, is the trade association representing approximately 300 manufacturers, marketers, and raw material suppliers in the herbal dietary supplements industry. AHPA will provide full written comments to the topic at hand at a later date.

OBJECTIVES BEYOND THE AGENCY'S STATED PRIORITIES

First, AHPA agrees that the Agency's stated objectives, safety and appropriate labeling, must remain as priorities. Industry must recognize its responsibility to conform to DSHEA in a manner that assures that these key objectives are met. In addition, FDA must be willing to use the regulatory and enforcement authority granted by DSHEA to protect consumers from those who would act otherwise.

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Second, AHPA believes that the Agency must recognize the full breadth of DSHEA's allowance of structure/function statements within the disease definition that existed at the time DSHEA was passed into law. AHPA believes that DSHEA clearly allows structure/function statements that address non-disease conditions such as sleeplessness, constipation, PMS, prostate enlargement, menopause, overweight, and tension, to name a few.

Third, the Agency should consider strategies to fully inform consumers about their broader health needs as related to these non-disease conditions. For example, a dietary supplement that contains saw palmetto might make a structure/function statement regarding the product's effect on the prostate. The consumer of such a product would be better informed if the product's label contained a statement to identify the prostate-related signals that are generally accepted to indicate the need to visit a healthcare professional.

AHPA has not designed a specific strategy for the development and utilization of such additional consumer information as is envisioned in this last suggestion, but it is important to recognize that the word "Education" in DSHEA is too often overlooked. We invite the Agency to take this idea seriously, and to open avenues of communication with all stakeholders in the development of such strategies.

PRIORITIES

AHPA suggests that the following tasks are priorities within the Agency's stated supplement strategy:

- Good manufacturing practices (GMP). Since the Industry Draft GMP for dietary supplements was published in the *Federal Register* in February, 1997, dietary supplement manufacturers have had the opportunity to evaluate these by initiating their implementation in manufacturing facilities. In the meantime, the GMP Working Group of FDA's Food Advisory Committee (FAC) has submitted its Report to the full FAC. This Report makes specific recommendations regarding record keeping and dietary ingredient identity testing.

The Agency should prioritize the completion of final GMP for dietary supplements in open communication with all stakeholders. AHPA suggests that the Agency communicate with industry to determine if any modifications to the Draft GMP might have become apparent from the past 2½ years of actual experience, and establish a December, 2000 goal for a Final GMP for dietary supplements.

The Agency should also give adequate consideration to the Report of the GMP Working Group. AHPA believes that good guidance for industry in the GMP related issues of ingredient identity and record keeping can be drawn from this Report.

- Adverse event reporting. The Agency should prioritize one specific revision to the current system for reporting and communicating adverse events that may be related to dietary supplements. AHPA reiterates here its written request that a redacted copy of all events posted in the current system be prepared simultaneous to such posting, as the Agency should assume that manufacturers will request a copy.
- Ephedra. As CFSAN has stated in its 1999 Program Priorities, the resolution of the issues related to products containing *Ephedra* must be a priority. AHPA does not believe, however, that these issues can or should be resolved by rulemaking. Such an approach will only assure that the unfortunate misappropriation of resources on *Ephedra*, both by the Agency and by industry, will continue. AHPA has joined other associations in recommending a specific solution that does assure consumer safety. AHPA strongly recommends an open dialogue among stakeholders to address the *Ephedra* issue.

LEVERAGING RESOURCES

FDA's limited resources can be leveraged by continuing to communicate openly with manufacturers of dietary supplements. Ongoing activities related to open communication are in place, such as the active role undertaken by FDA staff in the Methods Validation Program initiated by industry over the past two years. Both FDA and industry must work

to further these valuable interactions, to assure that the existing resources of the industry segment can be utilized to effectively meet the Agency's overall objectives.

Sometimes our resources are wasted, however, in countering inaccurate representations of the dietary supplements industry as an "unregulated" industry. FDA could assist in maintaining all of our energies on the work at hand by taking care in any of its publications and communications related to the dietary supplements industry to reflect the tone of real cooperation and responsibility undertaken by the majority of the industry since the passage of DSHEA.

Thank you.