

BEFORE  
THE UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

COMMENTS OF  
HERB PHARM, INC.  
PO box 116  
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ON THE FOOD AND DRUG  
ADMINISTRATION'S DRAFT GUIDANCE:

**“GUIDANCE FOR INDUSTRY: SUBSTANTIATION FOR DIETARY  
SUPPLEMENT CLAIMS MADE UNDER SECTION 403(r)(6) OF THE FEDERAL  
FOOD, DRUG AND COSMETIC ACT”**

January 6, 2005

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Herb Pharm, Inc. is a manufacturer and marketer of traditional-style botanical extracts. Our products are regulated by the US Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA). Herb Pharm, Inc. hereby submits comments to FDA in response to their draft guidance titled *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act* (Draft Guidance), docket No. 2004D-0466.

### **Background**

Botanical extracts along with other dietary supplements are regulated as foods as recognized by DSHEA. Dietary supplement manufacturers are permitted under DSHEA to make certain claims for their products relating to nutrition, the structure and function of the body and general well being (hereinafter claims). According to the FDA publications *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule and Guidance for Industry-Structure/Function Claims Small Entity Compliance Guide* (Small Entity Guidance), these claims must be truthful and not misleading, manufacturers are required to maintain adequate substantiation for each claim and the FDA disclaimer must be used.

Prior to the publication of the Draft Guidance, FDA had not defined “substantiation” or addressed the requirements for adequate substantiation. The Federal guide previously available with detailed information on support for claims was the Federal Trade Commission (FTC) publication titled *Dietary Supplements: An Advertising Guide for Industry* (FTC Guide) from 2001. The FTC Guide has been widely used by industry since its publication to develop claims, the substantiation for claims and related labeling and marketing.

### **FDA’s Draft Guidance**

FDA’s Draft Guidance describes the amount, type, and quality of evidence that FDA recommends a manufacturer have to substantiate a claim. In the Draft Guidance, FDA states their intent to “apply a standard for substantiating claims for dietary supplements that is consistent with the Federal Trade Commission’s (FTC’s) standard.” FDA’s use and application of the standard and approach for claim substantiation essentially overlooks one of the most important FTC claim categories for manufacturers of traditional-style products, namely traditional claims.

Section C2 of FTC's Guide expressly deals with claims "based on traditional use" and the tradition-based evidence that adequately supports these claims. The FTC model has come under widespread use in industry resulting in a significant investment in labeling and marketing materials and related labor. In this regard, lack of support from FDA for the FTC model of tradition-based claims will create a major burden on business.

One especially important and relevant concept is differentiation of the type and degree of the claim. In the FTC Guide, this is based on the claim presentation and resulting consumer expectation generated by the claim. In turn, the degree of evidence required to support the claim is based on that level of expectation. This concept is immediately applicable not only to traditional use claims but also to claims of general well being, which are allowed under DSHEA and yet nearly impossible to prove scientifically due to their subjective nature. We ask that FDA adopt the FTC model, at the minimum, as a starting point for allowing historic and tradition-based claim substantiation.

Informing consumers of traditional use is an important concept and practice in its own right. Properly defined traditional or historic use should be allowed as substantiation for claims clearly indicated as tradition-based. This concept applies to Native American cultures and the numerous traditional uses adopted into popular US medicine from these cultures. It also applies to traditional uses from around the world. These traditional sources provide the overwhelming majority of knowledge on botanicals worldwide. The vast amount of indigenous and traditional knowledge regarding botanicals is integral to the total body of knowledge concerning these materials, and the ability to communicate this information to the consumer is integral to DSHEA.

A number of developed countries have established product classifications that allow traditional claims, substantiated solely by traditional use, for botanicals and other materials. Allowing this type of product class helps to protect and disseminate indigenous knowledge. Among the countries and organizations that support traditional-based substantiation are Canada, Australia and the World Health Organization (WHO). While the US does not have a separate product class for these traditional-style goods, the same allowance can be made within DSHEA using clearly defined claims and the appropriate tradition-based supportive information. We strongly urge FDA to allow traditional claims supported solely by traditional use and to include this claim category in the final guidance.

## **SUMMARY**

Appropriate claims supported solely by tradition-based substantiation are valid and reliable, yielding competent claims that are both meaningful to and desired by the consumer. The FTC Guide has become the standard in developing claims and labeling materials, including tradition-based claims. We ask FDA to establish, at a minimum, the same traditional claim model as the FTC Guide. A

tradition-based claim category will allow clear, honest and accurate communication and education for consumers, which is an important goal of DSHEA. Adoption of such a model will also create consistency at the Federal level and allow US business to continue operating in a harmonized manner in the global market.

Respectfully submitted,

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Herb Pharm, Inc.