Docket No. 2004D-0466

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF

HERBALIST & ALCHEMIST, INC.
51 South Wandling Ave.
Washington, NJ 07882
908.689.9020
beth@herbalist-alchemist.com

ON THE FOOD AND DRUG ADMINISTRATION'S REQUEST FOR COMMENT ON DRAFT GUIDANCE:

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

Herbalist & Alchemist, Inc. submits the following comments in response to the Food and Drug Administration Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal, Food, Drug and Cosmetic Act [Docket No. 2004D-0466].

Herbalist & Alchemist is a manufacturer and marketer of traditional botanical products that are regulated as "Dietary Supplement Products" by the US Food and Drug Administration (FDA). For almost 25 years we have served traditional practitioners and others who seek high quality botanical products. As a small company in rural New Jersey, we have actively worked to anticipate all regulatory requirements associated with our class of products. We are active board members in the American Herbal Products Association (AHPA)—our CEO, Beth Lambert currently serves as Chairman of the Board. Our President and Herbalist, David Winston, AHG, is a traditional practitioner and educator who has been in practice for over 30 years. Trained in Cherokee, Chinese, Western and Eclectic Herbal protocols, he owns one of the largest private botanical libraries in the United States.

All of our structure/function claims are made in conformity with the Guidance as set forth in the FDA's "Guidance for Industry-Structure/Function Claims Small Entity Compliance Guide" which states on page 2:

"What requirements must I meet to make any of these types of claims for my dietary supplement?

> There are three requirements you must meet. First, the law says you can make these claims if you have substantiation that the claims are truthful and not misleading. You must have this substantiation before you make the claims. Second, you must notify FDA that you are using the claim within 30 days of first marketing your product. Third, the claim must include a mandatory disclaimer statement that is provided for in the law."

In addition we have been guided by the FTC's "Dietary Supplements: An Advertising Guide for Industry" which has a defined section on Page 20, "Claims Based on Traditional Use"

"Claims Based on Traditional Uses

Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms."

In reviewing FDA's draft guidance on substantiation for dietary supplement claims which is the subject of the comments, we note that the Agency seems to have omitted--in their

definition of "standard and approach" to collection of "amount, type and quality of evidence FDA recommends a manufacturer to have to substantiate a claim under section 403 (r) (6) of the act-- the value of information about the traditional uses of botanicals to substantiate claims for dietary supplements that contain botanical ingredients. However the FDA does state that it intends to apply a "standard…that is consistent with the Federal Trade Commission's…"

We believe that the "standard and approach" as outlined in the proposed guidance document is not only inconsistent with the FTC's, but with many other international standards that accommodate Traditional Use documentation. Our Trade Association, AHPA, is filing comments which outline guidance standards and models in many other countries, such as Canada and Australia, that have accepted indications of traditional uses. We support their comments.

In addition, there is a long history of traditional botanical use here in the US. And all previous documents with respect to guidance for Structure/Function Claims (notably the FTC document cited above and the Commission on Dietary Supplement Labels as discussed in the AHPA filing) accommodate Traditional Use.

We further point out that by not considering Traditional Use as justification for structure function—how are traditional practitioners able to properly communicate appropriate uses for simple, traditional products. We believe that without this indicative labeling, consumer confusion will be heightened. DSEA was passed to continue to allow access to these traditional remedies. Labeling was included to provide consumer clarity and helpful information.

With respect to the time estimates given to collect this information for structure function files, we find the estimate of "only about an hour to assemble information needed to substantiate a claim on a particular dietary supplement when the claim is widely known and established" to be low. Search, review and reading these materials as well as compilation and filing takes substantially more time and varies by materials selected. And that especially for traditional botanicals the references are more often than not "found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases…" This does raise the issue of defining a "qualified collector"—one who is trained in traditional practice and is able to read, understand and if necessary explain, the knowledge found in such texts.

We also disagree that there "are no capital costs or operating and maintenance costs associated with this information collection". We use staff support, copying and scanning equipment and electronic storage and file storage for this effort. All of which take staff time and have operating costs to maintain. The capital cost to maintain a significant Botanical Library collection of historical references and current scientific journals is quite significant. In addition, constant review of all current literature for any scientific developments, takes additional staff time.

We believe that the FDA should broaden its “standard and approach” to accommodate the responsible collection and presentation of information related to the Traditional Uses of Botanicals to support Structure/Function Claims. And recognize that the collection of such information involves an investment of considerable knowledge and time on the part of the collector.