



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN 29 2007

Ms. Sara A. McGarvey
Quality Assurance Technician
Botanical Laboratories
1441 West Smith Road
Ferndale, Washington 98248

Dear Ms. McGarvey:

This is in response to your letters of January 5, 2007 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) concerning the products **Throat Spray Peppermint and Willow Garlic Ear Oil**.

These two products do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as dietary supplements. Rather, these two products appear to be drugs under the Act. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is applied externally or that elicits its intended affect on the body prior to being swallowed is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

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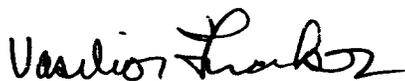
Page 2 - Ms. Sara A. McGarvey

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, products that are intended to be used externally (for example, the ear oil with appears to be intended to introduced into the ear) or that elicits its effect prior to being swallowed (for example, the throat spray to soothe a sore throat) are not subject to regulation as dietary supplements because they are not "intended for ingestion" and are drugs under 21 U.S.C. 321(g)(1) because they are articles (other than food) intended to affect the structure or function of the body or are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. If you intend to market a product such as this, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

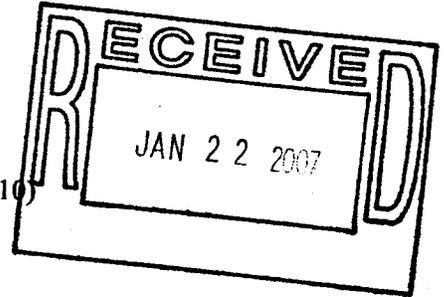
FDA, Seattle District Office, Office of Compliance, HFR-PA340

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Science For A Healthier Tomorrow

January 5, 2007

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3825



Dear Sir or Madam,

This notification is on behalf of Herbs for Kids® and parent company Botanical Laboratories, Inc., 1441 West Smith Road, Ferndale, WA 98248.

We intend to include the following statements of nutritional support based on substantiated data for the use of Calendula Flowers on the following products.

Ingredient: Calendula flowers
Statements: Soothes ear discomfort
Products: Willow Garlic Ear Oil

Please be advised that the information contained herein is accurate to the best of our knowledge and information. Our firm has information substantiating that the above statements are truthful and not misleading.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Sara A. McGarvey".

Sara A. McGarvey
Quality Assurance Technician
Botanical Laboratories, Inc.

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Science For A Healthier Tomorrow



January 5, 2007

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3825

Dear Sir or Madam,

This notification is on behalf of Herbs for Kids® and parent company Botanical Laboratories, Inc.,
1441 West Smith Road, Ferndale, WA 98248.

We intend to include the following statements of nutritional support based on substantiated data for
the use of Licorice Root on the following products.

Ingredient: Licorice root
Statements: Soothes sore throats
Products: Throat Spray Peppermint

Please be advised that the information contained herein is accurate to the best of our knowledge and
information. Our firm has information substantiating that the above statements are truthful and not
misleading.

Sincerely yours,

Sara A. McGarvey
Quality Assurance Technician
Botanical Laboratories, Inc.