



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR 11 2005

Mr. Kevin H. Cobb
Director of Marketing
ZAND Herbal Formulas
Botanical Laboratories, Inc.
1441 West Smith Road
Ferndale, Washington 98248

Dear Mr. Cobb:

This is in response to your letter to the Food and Drug Administration (FDA), dated February 4, 2005, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that ZAND, a division of Botanical Laboratories, Inc., intends to make several claims for the ingredient echinacea in a product described as "HerbalMist Throat Spray."

This letter is to advise you that this product may not meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, may not be able to be marketed as a dietary supplement. 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 topically to the throat (as a spray) and that elicits its affect 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:

97S 0133 LET 815

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.”)...

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, a product that is applied topically to the throat (i.e., as a throat spray) to elicit a response before being swallowed is not subject to regulation as dietary supplements because it is not “intended for ingestion” and may be a drug under 21 U.S.C. 321(g)(1)(C) because it is an article (other than food) intended to affect the structure or function of the body.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
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, Compliance Branch, HFR-PA340

Botanical
LABORATORIES
Consumer Products Division

February 4, 2005

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

FEB 16

Dear Sir or Madam,

This notification is on behalf of ZAND® 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 Echinacea on the following product.

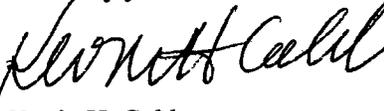
Ingredient: Echinacea

Statements: Immune Support
Supports a healthy immune system
Supports the immune system
Increased immune support

Product: Insure Immune Support
Organic Insure Immune Support
Echinacea Root Extract
Standardized Echinacea Root
Standardized Echinacea & Goldenseal Root
Kids Insure Herbal
Echinacea PM
HerbalMist Throat Spray

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,



Kevin H. Cobb
Director of Marketing
ZAND® Herbal Formulas
Botanical Laboratories, Inc.

90897

ZAND

HERBS for KIDS

NatraBio

bioAllers