



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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JAN 15 2004

Ms. Sara Katz  
President  
Herb Pharm  
P.O. Box 116  
Williams, Oregon 97544

Dear Ms. Katz:

This is in response to your letter to the Food and Drug Administration (FDA), dated January 6, 2004, 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 Herb Pharm is making the following claim for the product **Oral Health Tonic**:

“Oral Health Tonic. Herbal Mouthwash for Healthy Gums.”

This product does 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 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 dietary, and are labeled as a dietary supplement.

An article that is delivered orally, but that exerts its effect prior to being swallowed (for example, as a mouthwash that will act directly on the gums, 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

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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 intended to have its effect before it is ingested is not subject to regulation as a dietary supplement because it is not "intended for ingestion" and is 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.

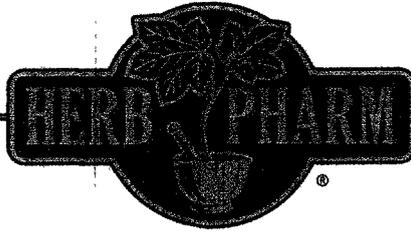
Sincerely yours,



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-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Office, Compliance Branch, HFR-PA340



Office of Special Nutritionals (HFS-450)  
Center for Food and Safety  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

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1.6.2004

Re: Notice of (a) structure/function statement(s) on a dietary supplement.

(i) Name and address of manufacturer:

HERB PHARM • PO BOX 116 • WILLIAMS, OR 97544

(ii) Text of statement:

"Oral Health Tonic. Herbal Mouthwash for Healthy Gums."

(iii) Dietary ingredient:

Cranberry  
(*Vaccinium macrocarpon*)

(iv) Dietary supplement:

Liquid Herbal Extract:  
Oral Health Tonic

(v) Brand name:

HERB PHARM

I hereby certify that the information contained in this notice is complete and accurate and that Herb Pharm has substantiation that the statement is truthful and not misleading.

A handwritten signature in cursive script that reads "Sara Katz".

Sara Katz  
President of Herb Pharm

CC: 2/FDA, 1/FILE

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