



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 13 2003

1 3 8 1 '03 MAR 24 P 1:52

Guru Hari S. Khalsa
Director Technical Services
Golden Temple of Oregon, Inc.
2545-A Prairie Road
Eugene, Oregon 97402

Dear Mr. Khalsa:

This is in response to your letter to the Food and Drug Administration (FDA), dated January 21, 2003, 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 Golden Temple of Oregon, Inc. is making the following claims, among others, for the product **Throat Comfort®**:

“Coats and Soothes Irritated Throat;
...soothe mucous membranes in the trachea...;
“...relieving minor irritation in the mucous membranes of the throat.

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, to soothe the throat and relieve throat irritation) 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:

975-0163

LET 67

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



Golden Temple of Oregon, Inc.
2545-A Prairie Rd., Eugene, Oregon 97402
Tel.: 541-461-2160 Fax: 541-461-1633

Date: 1/21/03

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

JAN 28 2003

This certification is filed in accordance with the Food and Drug Administration regulation 21 C.F.R. 101.93 (a) (3).

I certify that the information in the attached notification is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

By 
Guru Hari S. Khalsa

Director Technical Services

83284

5. Warming herbs such as Cardamom Seed, Coriander Seed, Ginger Root and Black Pepper also support gastrointestinal function as they help reduce gas and move food through the digestive tract comfortably.
6. While Cardamom is especially good for helping the body digest cold and sweet foods, Ginger Root is known for its effectiveness in reducing nausea associated with over-indulgence.
7. Peppermint Leaf is a relaxant for the muscles of the intestinal wall.
8. Minor upset stomach relief; relieves occasional indigestion, heartburn and gas.
9. helps relieve the discomfort of the stomach and intestinal tract.

* * * * *

Name of Dietary Supplement

Throat Comfort®

Name of dietary Ingredients

Organic Licorice Root, Organic Fennel Seed , Black Cherry Bark, Organic Cinnamon Bark, Organic Orange Peel, Slippery Elm Bark, Organic Cardamom Seed, Organic Ginger Root, Organic Mullein Leaf, Organic Black Pepper, Organic Clove Bud

Statements of Nutritional Support for the Dietary Supplement

1. Coats and Soothes Irritated Throat;
2. designed to support the respiratory system and soothe mucous membranes in the trachea, irritated by common, everyday stress;
3. Our healing formula is made with Slippery Elm Bark and Mullein, favorite demulcents of Western and European herbalism prized for their mucilage content and usefulness in relieving minor irritation in the mucous membranes of the throat.
4. help suppress spasms and soothe the muscles lining the bronchioles;
5. To support respiratory function, the recipe has also been augmented with organic Licorice (*Glycyrrhiza glabra*) and warming spices.

* * * * *

Name of Dietary Supplement

Woman's Energy Lift™

Name of Dietary Ingredients

Dong Quai Root Extract, Lingustilides (1%), Organic Ginger Root, Organic Cinnamon Bark, Organic Fennel Seed, Organic Orange Peel, Organic Chamomile Flower,