

Food and Drug Administration Washington, DC 20204

8533 OH AUG-8 P2:21

AUG - 3 2001

Ms. Cindy K. Anghof Group Team Leader, Research Tom's of Maine Lafayette Center P.O. Box 710 Kennebunk, Maine 04043-0710

Dear Ms. Anghof:

This is in response to your letter to the Food and Drug Administration (FDA), dated July 25, 2001, 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 Tom's of Maine is making the following claims, among others, for the following products:

Natural Bronchial Syrup for Children Natural Bronchial Syrup for Adults

- "To help loosen bronchial passages and to soothe a dry throat:
- ...promoting clear and healthy bronchial passages"
- "Support clear and healthy bronchial passages"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely upper respiratory tract disorders. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

These products also 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. We explain the basis for our opinion below.

975-0163

LET 536

Page 2 - Ms. Cindy K. Anghof

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, a syrup that is intended to soothe the throat) 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 <u>United States v. Ten Cartons, Ener-B Nasal Gel</u>, 888 F. Supp. 381, 393-94 (E.D.N.Y.), <u>aff'd</u>, 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.")...

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)(i). 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.

Page 3 - Ms. Cindy K. Anghof

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

Director

Division of Compliance and Enforcement 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, New England District Office, Compliance Branch, HFR-NE240

11077



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, D.C. 20204

July 25, 2001

This letter is intended to serve as official notification that Tom's of Maine, P.O. Box 710, Kennebunk, ME has begun to market the following dietary supplement products bearing statements of nutritional support as indicated:

Product name	Dietary supplement	Statement of nutritional support
Natural Bronchial Syrup For Children	Extract of Thymus vulgaris L., flowering herb	"to help loosen bronchial passages and to soothe a dry throat" "gently stimulate the mucous
		membranes of the respiratory tract, promoting clear and healthy bronchial passages"
		"support clear and healthy bronchial passages"
Natural Bronchial Syrup	Extract of Thymus vulgaris L.,	"to help loosen bronchial passages
For Adults	flowering herb	and to soothe a dry throat"
		"gently stimulate the mucous
		membranes of the respiratory tract,
		promoting clear and healthy bronchial
		passages"
		"support clear and healthy bronchial
		passages"

Group Team Leader, Research

7/25/01 Date