

7911 '01 JUN 11 P2:05  
JUN - 7 2001

Jay H. Geller, Esq.  
West Tower  
Suite 4000  
2425 West Olympic Boulevard  
Santa Monica, California 90404

Dear Mr. Geller:

This is in response to your letter to the Food and Drug Administration (FDA) dated May 17, 2001 on behalf of Traditional Medicinals, Inc. In your letter, you stated that Traditional Medicinals, Inc. disagrees with FDA's view that certain claims that we identified in a letter dated March 30, 2001 suggest that certain of their products are intended to treat, prevent, cure, or mitigate disease. You stated that neither of the label claims we cited in our letter are disease claims but instead are simply claims that refer to a function of the body, namely, breathing.

We disagree. We concede that not all claims of the type that were the subject of the notification submitted by Traditional Medicinals, Inc. are necessarily disease claims under the Federal Food, Drug, and Cosmetic Act (the Act). In the preamble to the final rule on structure or function claims (see 65 FR 1000 at 1011, January 6, 2000), FDA stated that the context in which a claim is presented is important to determination whether a statement is a disease claim or is a structure or function claim. We stated that the context in which a claim appears can provide evidence in either direction; that is, whether the claim is a disease claim or a structure or function claim.

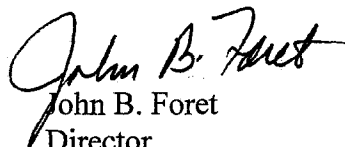
In the March 21, 2001 letter to Traditional Medicinals, Inc., we informed the firm that we consider the claims "promotes relaxed nighttime breathing" and "supports clear breathing" to be implied claims to treat, prevent, cure, or mitigate diseases, namely, signs or symptoms of the common cold. Our conclusion was based on the context in which the claims were being made, namely, that the claims evidence that the products were intended for use to treat or mitigate signs and symptoms of colds. The fact that other products are marketed using the word "cold" in connection with claims made for them does not, as you seem to assert, alter the fact that a particular claim is or is not a disease claim under the Act. Consequently, we are not persuaded that the conclusion expressed in our March 30, 2001 letter is incorrect and we stand by our original determination that the claims proposed in the original submission from Traditional Medicinals, Inc. are disease claims that subject their products to regulation under the drug provisions of the Act.

Page 2 - Mr. Jay H. Geller

Please contact us if we may be of further assistance.

Sincerely,

---



John B. Foret

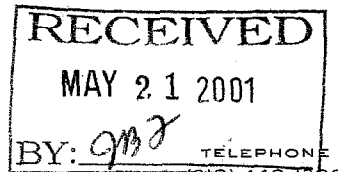
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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, San Francisco District Office, Compliance Branch, HFR-PA140



LAW OFFICES OF  
JAY H. GELLER  
A PROFESSIONAL CORPORATION  
WEST TOWER, SUITE 4000  
2425 WEST OLYMPIC BOULEVARD  
SANTA MONICA, CALIFORNIA 90404

May 17, 2001

Mr. John B. Foret  
Director, Division of Compliance  
and Enforcement  
Office of Nutritional Products,  
Labeling and Dietary Supplements  
Center for Food Safety and Applied  
Nutrition  
Food and Drug Administration  
Washington, D.C. 20204

Dear Mr. Foret:

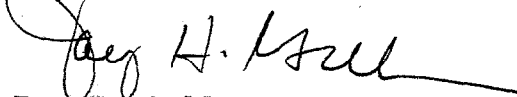
Your letter of March 30, 2001 to Traditional Medicinals, Inc. regarding its product GYPSY COLD CARE and COLD CARE P.M. has been referred to me for a reply. Please be advised as follows.

The company disagrees with your characterization of the two claims cited in your letter. Neither claim relates to diagnosis, treatment, cure, or prevention of any disease. The claims simply refer to a function of the body, namely, breathing.

As to your statement with regard to the word "COLD" appearing in the name of the products, I call your attention to the dozens of dietary supplements that are marketed with the word "COLD" as part of the name. Attached are internet printouts from the Stash Tea website for its STASH COLD CARE TEA, the Triple Leaf Tea website for its COLD & FLU TIME HERBAL TEA, the Wide Awake Coffee & Tea website for Great Earth Medicinals TEA FOR COLDS, and from the reach4life.com website for Nature's Way COLD CARE DAYTIME ENERGY and COLDCARE NIGHTTIME REST. In addition, from the reach4life.com website, the following supplements are available with the word "cold" as part of the product name: ColdFlua, Cold Formula III, Cold Control, Cold & Flu, and Cold Season. Furthermore, from the U.S. Trademark Office database, the following trademarks are registered for dietary supplements with the word "cold" as part of the registered trademark: COLD CHASER; COLD ACTIVE; COLD WAR; COLD & FLU SPA; COLD FIGHTERS; COLD DEFENSE; COLD-CONTROL; and ZINC-A-COLD. The use of the word "cold" in connection with dietary supplements as nutritional support statements is a very common practice.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

  
Jay H. Geller

JHG:mk  
Encls. a/s  
cc: Lynda Sadler