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George A. Eby
George Eby Research
2109 Paramount Avenue
Austin, Texas 78704

Dear Mr. Eby:

This is in response to your FAX of February 6, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement in the labeling of the product "Fast Dry™ Zinc Lozenges."

Fast Dry™ Zinc Lozenges release zinc ions. In vitro, zinc ions are antirhinoviral agents, T-Cell lymphocyte nutrients, interferon inducers, anti-inflammatory and drying aides.

We would point out that section 403(r)(6) of the act 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 statement that you are making for "Fast Dry™ Zinc Lozenges" suggests that this product is intended for at least one of these purposes, in that it claims to be an antirhinoviral agent and an anti-inflammatory agent. Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for other than food use within the meaning of section 201(g) of the act and that it is subject to regulation under the drug provisions of the act. Furthermore, references in your labeling to articles that state that zinc lozenges may be used to treat common colds would appear also to establish that this product is intended for drug use within the meaning of section 201(g)(1)(B) 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.

Sincerely yours,

John Gordon
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Dallas District Office, Office of Compliance, HFR-SW1

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

GER

Facsimile Cover Sheet

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Date: 02/06/96

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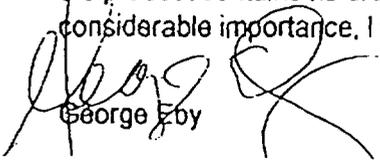
Dr. Gordon:

Will you please examine the enclosed proposed label for Fast Dry(tm) Zinc Lozenges to see if it meets the criteria set out in the Dietary Supplement Health and Education Act of 1994. Pursuant to the Act, the following Statement of Nutritional Support for Fast Dry™ Zinc Lozenges under the provision for statements SHOWING THE ROLE OF DIETARY INGREDIENTS INTENDED TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY is as follows:

Fast Dry™ Zinc Lozenges release zinc ions. In vitro, zinc ions are antirhinoviral agents, T-Cell lymphocyte nutrients, Interferon inducers, anti-inflammatory and drying aides.

In my letter to your office dated December 8, 1995, I enclosed a copy of my book entitled HANDBOOK FOR CURING THE COMMON COLD - THE ZINC LOZENGE STORY, and two 1995 articles concerning use of zinc lozenges to either abort incipient colds, or reduce the duration of colds by an average of 5 to 7 days dependent solely upon the zinc ion availability (ZIA) value of the lozenges. Those 3 references cite articles by others documenting the in vitro effects of zinc ions. The article I cite on the label reports my findings on efficacy of zinc lozenges having various formulations (balanced literature).

I want to order labels tomorrow, and would appreciate a telephone call to discuss the matter. I am seeking a major pharmaceutical company to license my patent U.S. Patent Number 5,409,905, entitled CORE FOR COMMON COLD. Obviously, they would file a New Drug Application for the product. Since the product contains no drugs and can be considered a dietary supplement with drug properties of considerable importance, I want to make the product available to the public now, while we wait for an NDA.


George Eby

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