



Rec'd 3/26/98

MAR 13 1998

Mr. Chris Burns
Manager, Sales and Marketing
Nutro Laboratories, Inc.
650 Hadley Road
South Plainfield, New Jersey 07080

Dear Mr. Burns:

This is in response to your letter of April 22, 1997 to the Food and Drug Administration (FDA) 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 Nutro Laboratories, Inc. is making the following claim, among others, for the product:

Life's Finest Cold Comfort™ Zinc Lozenges

"Studies show that Zinc Gluconate lozenges can help stabilize and maintain healthy secretory cell membranes."

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 inclusion of the term "cold comfort" in the product name suggests that it is intended to prevent, treat or mitigate a disease, namely the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of

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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.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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 Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456;jel:3/13/98:docname:52320.adv:disc26



4/22/97

April 22, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St SW
Washington DC 20204

Notification of the Use of a Statement of Nutritional Support

This is to serve as notification to the Agency, that Nutro Laboratories Inc, 650 Hadley Road, South Plainfield, NJ 07080, has in the last 30 days first marketed its' product, *Life's Finest Cold Comfort™ Zinc Lozenges*. The label includes the following statement of nutritional support

"Studies show that Zinc Gluconate lozenges can help stabilize and maintain healthy secretory cell membranes."

The dietary ingredient that is the subject of the statement is Zinc Gluconate

The statement is followed by the disclaimer:

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Sincerely,


Chris Burns
Manager, Sales & Marketing

cc: Daniel Marcus, Wilmer, Cutler & Pickering

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