



OCT - 9 1997

0767 '97 DEC 16 P1:37

Mr. Jeffrey L. Bower
Vice President - Operations
J.B. Williams Company, Inc.
65 Harristown Road
Glen Rock, New Jersey 07452

Dear Mr. Bower:

This is in response to your letter of September 25, 1997 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 J.B. Williams Company, Inc. is making the following claim for the product "Cepacol Cold Care Zinc Acetate Lozenges:

 Taken as a dietary supplement, Cepacol Cold Care helps promote general well-being during the cold season.

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 this product and the name of the product (i.e., Cepacol Cold Care), taken together, suggest that it is intended to treat, mitigate, or prevent a disease, namely the common cold. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and it is subject to regulation under the drug provisions of the act. If you intend to make a claim 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

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, Compliance Office, HFR-MA340

JB Williams COMPANY, INC.

September 25, 1997

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

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Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement Cepacol® Cold Care™ Zinc Acetate Lozenges.

On the back label we state, "Taken as a dietary supplement, Cepacol Cold Care helps promote general well-being during the cold season.*" The asterisk in the previous statement refers to the following statement which is also on the back panel, in an outlined box and in bold print, "* 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,



Jeffrey L. Bower
Vice President - Operations

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