



MAR 13 1998

*Rec'd 3/26/98 jt*

Mr. Don Jantzen  
Director, Regulatory Affairs  
Adams WorldWide R&D  
Warner-Lambert Company  
170 Tabor Road  
Morris Plains, New Jersey 07950

Dear Mr. Jantzen:

This is in response to your letter of September 18, 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 Warner-Lambert Company is making the following claim, among others, for the product "Halls Zinc Defense Cold Season Dietary Supplement:"

"Halls Zinc Defense is a dietary supplement which defends against dietary zinc insufficiency, for use during the cold season or throughout the year."

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 statement that you are making for this product, including the inclusion of the term "cold season" in the product name, suggest 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). The 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 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

975-0163

LET 139

**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)  
r/d:HFS-456:RMoore:3/12/98  
Init:GCF-1:LNickerson:3/12/98  
f/t:HFS-456:sar:3/13/98:docname:warner.adv:disc26

Warner-Lambert Company  
170 Tabor Road  
Morris Plains, New Jersey 07950

201 540-2000  
Cable Address: WARNLAM MORRISPLAINS  
Telex: 136424 (WARNERLAM MOPS)

**WARNER  
LAMBERT**

September 18, 1997

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

RECEIVED  
9/23/97

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, this letter serves as 30 day notification that Warner-Lambert Company has commenced marketing Halls® Zinc Defense™ Cold Season Dietary Supplement, which contains the ingredient, zinc acetate, and the label of which bears statements of nutritional support.

The statements of nutritional support are as follows:

"Supports your natural resistance system"

"Halls Zinc Defense is a dietary supplement which defends against dietary zinc insufficiency, for use during the cold season or throughout the year. Zinc is an essential nutrient which plays an important role in the functioning of the body's natural resistance system."

The undersigned certifies that the information contained in this notice is complete and accurate, and that Warner-Lambert Company has substantiation that the statements are truthful and not misleading.

Thank you for your attention to this matter.

Sincerely,



Don Jantzen  
Director, Regulatory Affairs  
Adams WorldWide R&D

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