



SEP 29 2004

Mr. Micah S. Portney  
President  
ZEO Health Ltd.  
29 Sunset View Drive  
West Nyack, New York 10994

Dear Mr. Portney:

This is in response to your letter of September 20, 2004 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 ZEO Health Ltd. is making the following claims for the product Esdifan™ :

“Stops diarrhea.”

“Relieves diarrhea.”

“Prevents diarrhea.”

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 statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely diarrhea. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975-0163

ZBT 785

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

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-310

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

FDA, New York District Office, Office of Compliance, HFR-NE140



ZEO Health Ltd.

September 20, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, I-IFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5 100 Paint Branch Parkway  
College Park, MD 20740

RECEIVED  
9/23/04

Re: Label Claims/Disclaimers

Dear Mr. Moore:

This letter shall serve as notification that the following product is manufactured by ZEO Health, Ltd., with offices at 29 Sunset View Drive, West Nyack, New York 10994 bears a label that contains a statement provided by § 403(r)(6) of the Federal Food, Drug and Cosmetic Act (the "Act"). ZEO Health, Ltd. wishes to comply with said section of the Act. This notification is being made no later than thirty (30) days after the first marketing of the product.

<u>NAME OF PRODUCT</u>	<u>STATEMENTS</u>	<u>INGREDIANTS TO WHICH THE STATEMENTS REFER</u>
<b>Esdifan™</b>	<b>Stops diarrhea. Relieves diarrhea. Prevents diarrhea.</b>	<b>Zeolite - clinoptilolite Vitamin B12 Calcium</b>

29 Sunset View Drive  
West Nyack, New York 10994  
(845) 353-5185

#763



## ZEO Health Ltd.

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I certify that the information contained in this notice is complete and accurate and that ZEO Health, Ltd. has substantiation that the statements are truthful and not misleading.

If you have any questions, please feel free to contact me.

ZEO Health, Ltd.

By: 

Name: Micah S. Portney

Title : President