



0358 10-138-6 2004

NOV - 1 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 October 4, 2004. Your letter responded to our September 29, 2004 concerning claims being made your product Esdifan™. These claims were the subject of a notification to FDA under 21 U.S.C. 343(r)(6) and 21 CFR 101.93.

In our September 29, 2004, we stated that the claims "Stops diarrhea," "Relieves diarrhea," and "Prevents diarrhea" suggested that the product is intended to treat, prevent, or mitigate a disease, namely diseases for which diarrhea is a characteristic sign or symptom, and that the product that was the subject of the claims, Esdifan™, appeared to be subject to regulation under the drug provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

In your letter, you assert that diarrhea "is a symptom of another cause" such as "specific diseases, such as Irritable bowel Disease or Crohn's Disease, from bacterial or viral infection, or a symptom or side effect of taking a drug or antibiotic." For this reason, you ask FDA to reconsider the position set forth in our September 29, 2004 letter that diarrhea is a disease which subjects your product to regulation under the drug provisions of the Act and affirm to you that the diarrhea claims that were the subject of your notification are within the scope of claims that may be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Act).

We disagree with your assertion that diarrhea is not a disease as that term is defined in 21 CFR 101.93(g)(1). For purposes of 21 U.S.C. 343(r)(6), a "disease" is defined as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g. cardiovascular disease) , or a state of health leading to such dysfunctioning (e.g., hypertension)." See 21 CFR 101.93(g)(1). The regulation also states that "FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease...if it meets one or more of the criteria listed below...." The regulation also states that FDA will consider the context in which the claim is made and that a claim may implicitly or explicitly be a disease claim. Among other criteria, a claim may be a disease claim if it is a claim that the product "has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology" (21 CFR

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Page 2 - Mr. Micah S. Portney

101.93(g)(2)(ii) or “treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse event constitute diseases” (21 CFR 101.93(g)(2)(ix).

You state that diarrhea is a “symptom of another cause” which may be specific diseases such as Irritable Bowel Disease or Crohn’s Disease, infectious diseases, or a consequence of drug or antibiotic therapy. Diarrhea is unambiguously a consequence of damage to a system (the gastrointestinal system) such that it does not function properly, the dysfunction being evidence by the diarrhea<sup>1</sup>. That it is a characteristic sign or symptom of various diseases places it squarely within the scope of the definition of “disease” in 21 CFR 101.93(g). We continue to believe that the position set forth in our September 29, 2004 letter is correct and that claims that a product is intended for use to diagnose, mitigate, treat, cure, or prevent diarrhea cause the product to be subject to regulation as a drug.

You also state in your letter that an FDA employee verbally stated that claims about a product’s affect on diarrhea would be appropriate structure or function claims because diarrhea is a symptom and not a disease. We regret any confusion that may have been caused by the information you received concerning your proposed claims. However, it is important to recognize that whether a particular statement is or is not a disease claim depends on the context in which the statement is made. Statements about conditions, including symptoms, that may result from many causes, both disease and non-disease, may be able to be made in dietary supplement labeling under 21 U.S.C. 343(r)(6) if the claim makes clear that the product is only intended to affect the non-disease condition or symptom. In that your claim does not include such qualifying context, it remains a disease claim.

Please contact us if we may be of further assistance.

Sincerely yours,

*for Robert Moore*  
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

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<sup>1</sup>“An abnormally frequent discharge of semisolid or fluid fecal matter from the bowel”  
Stedman’s Medical Dictionary, 26<sup>th</sup> edition.

Page 3 - Mr. Micah S. Portney

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.

October 4, 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

OCT 18 2004

Re: *Label Claims/Disclaimers*

To Whom It May Concern:

This letter is in response to your letter, dated September 29, 2004, responding to our 30 day notification for labeling claims.

According to every medical dictionary, diarrhea is a symptom of another cause. The cause can be due to specific diseases, such as Irritable Bowel Disease or Crohn's Disease, from bacterial or viral infection, or a symptom or side effect of taking a drug or antibiotic.

We contacted your office and received a verbal response from Angela Pope on 4/21/2004 stating that your office, and that of the FDA, takes the position that diarrhea is a symptom and not a disease and therefore can be used in structure function claims. An associated legal firm also called Ms. Pope for confirmation on 4/22/2004, inquiring with the same question about the position the FDA takes on the definition of diarrhea for labeling, and received the same answer that diarrhea is a symptom of a disease and not a disease in and of itself.

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West Nyack, New York 10994  
(845) 353-5185

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**ZEO**

SUPPORTS A HEALTHY BODY

**ZEO Health Ltd.**

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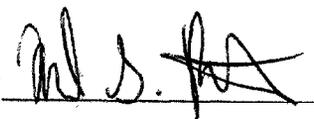
We have included in this letter, for your further consideration, a copy taken from the website of the FDA, clearly stating and listing diarrhea as *symptom* of other causes, and not a disease. We respectfully request that you reconsider your position as stated in the September 29, 2004 letter in light of this additional, supporting documentation. We are hopeful that the outcome of this reconsideration is consistent with the prior confirmations we were given.

OCT 18 2004

Thank you in advance for your continued cooperation. We are eager and willing to continue to comply with the guidelines as set by the FDA.

If you have any questions or need further information, please feel free to contact me.

ZEO Health, Ltd.

By: 

Name: Micah S. Portney

Title : President