



OCT - 7 2002

President  
Trader Joe's Company  
Corporate Office  
Post Office Box 5049  
Monrovia, California 91017-7149

Dear Sir/Madam:

This is in response to your submission to the Food and Drug Administration (FDA), dated September 5, 2002. Your submission appears to be intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a).

Nonetheless, in resubmitting your notification, you should be aware that the product bears claims that do not appear to be claims subject to 21 U.S.C. 343(r)(6).

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, namely that it is "an all natural antacid for upset stomach" and the use of the term "antacid" in the name of the product, suggests that it is intended to treat, prevent, or mitigate a disease,

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heartburn<sup>1</sup>. 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



John B. Foret  
Director  
Division of Compliance and Enforcement  
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-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

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Although FDA concluded that "occasional heartburn" and "occasional acid indigestion" may be nonspecific symptoms that could be appropriate structure/function claims, the claim for your product is not qualified such that it is not a disease claim. (see 65 FR 1000 at 1031; Jan. 6, 2000).

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**TRADER JOE'S** COMPANY  
*Unique foods and beverages at prices everyone can afford*

CORPORATE OFFICE  
P.O. BOX 5049  
MONROVIA, CA 91017-7149  
(626) 599-3700

September 5, 2002

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204



Dear Sirs:

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Distributor's name and address: Trader Joe's Company, P.O. Box 5049, Monrovia, CA 91017

Statement: Trader Darwin's Chewable Antacid Dophilus Calcium Tablets are an all natural antacid for upset stomach.

Dietary ingredients: Calcium (Calcium Ascorbate), Proprietary Blend of: (Lactobacillus Acidophilus, Lactobacillus plantarum, Lactobacillus bulgaricus, Lactobacillus casei)

Name of the supplement bearing the label or associated with the labeling: (Trader Darwin's Antacid Dophilus Calcium Dietary Supplement sku # 00531085)

Respectfully submitted,

Trader Joe's Company

SUGGESTED USE

TRADER DARWIN'S®

**ANTACID**  
Dop plus Calcium

0053 1085

**Supplement Facts**  
Serving Size 2 tablets  
Servings Per Container 30

Amount Per Serving	% Daily Value*	
Calories 10	Calories from Fat 0	
<b>Total Carbohydrate</b>	2g	0%
Sugars	2g	
Calcium (as calcium ascorbate)	250mg	25%
Vitamin D-3 (as cholecalciferol)	100 IU	25%
Magnesium (as magnesium oxide)	125mg	30%
A Proprietary Blend of: Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus bulgaricus, Lactobacillus casei	100mg	**
FOS Microflora Growth Concentrate***	50mg	**
FOS Fructooligosaccharides derived from natural plant sources		

\* Daily Value not established.  
\*\*\* FOS is an all natural carbohydrate found in a variety of fruits, vegetables and grains.

Other Ingredients: Dextrose, Fructose, Stearic Acid (Vegetable Source), Bilberry Extract, Natural Cherry Flavor, Silica, Mint. Dist & Sold Exclusively By Trader Joe's, Monrovia, CA 91016