



2/25/97

February 24 1997

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

0033 '97 SEP 19 P1:29

Dear Sir:

This is to inform you that Mission Pharmacal Company has included a statement under section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act on the label of our product, CALCET. The following information is submitted ( original and two copies) as per the Food and Drug Administration proposed rule published in the September 27, 1996 Federal Register (61FR 50771-4) [Docket No. 96N-0240].

Name of Manufacturer: Mission Pharmacal Company  
P. O. Box 786099  
San Antonio, TX 78278 6099

Text of Statement: "for low calcium  
Leg cramps"

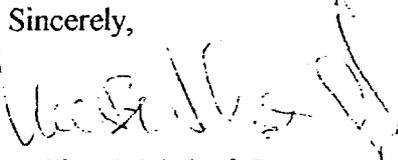
Name of dietary ingredient: calcium carbonate, calcium lactate, and calcium gluconate

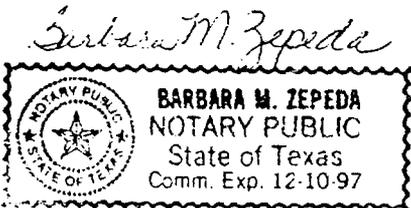
Name of Dietary Supplement: CALCET Dietary Supplement  
Triple Calcium plus Vitamin D

The information contained in this notice is complete and accurate and as an official of Mission Pharmacal Company, I certify that we have substantiation that the statement is truthful and not misleading.

Enclosure:  
Label

Sincerely,

  
Neill B. Walsdorf, Jr.  
Vice President



975-0162

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**DIRECTIONS FOR USE:** Two tablets at bedtime. Two tablets on arising. Do not exceed 4 tablets a day except on the advice or recommendation of your physician, pharmacist or health professional.

**WARNINGS:** KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.

**THIS IS A SAFETY SEALED PACKAGE, FOR YOUR PROTECTION.** Do not use this product if inner seal is broken.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.*

for low calcium  
**Leg cramps\***  
**Calcet**  
 Ⓢ Dietary Supplement  
**Triple Calcium  
 plus Vitamin D**

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100 Coated Tablets

**Supplement Facts**  
 Serving Size: 2 Tablets

	Amount Per Serving	% Daily Value
Vitamin D <sub>3</sub>	200 IU	50%
Calcium (as calcium carbonate, calcium lactate, calcium gluconate)	300 mg	30%

**Ingredients:** Calcium carbonate, calcium lactate, calcium gluconate, sugar, polyethylene glycol, croscarmellose sodium, povidone, color added, magnesium stearate, yellow 5 lake, carnauba wax, white beeswax, cholecalciferol, sodium benzoate.

**Mission PHARMACAL** San Antonio, TX, USA 78278-6099  
 E7 Rev 01/960

