



JAN 14 2002

Ms. Jill K. Jarusiewicz  
Manager, Regulatory Affairs  
Novartis Consumer Health, Inc.  
560 Morris Avenue  
Summit, New Jersey 07901-1312

Dear Ms. Jarusiewicz:

This is in response to your letter of January 7, 2002 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 Novartis Consumer Health, Inc. is making the claim "May reduce the risk of osteoporosis" for its product **Maalox® DS Softchews**.

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if you require further assistance.

Sincerely,

for 

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 565

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**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 Compliance, HFR-MA340

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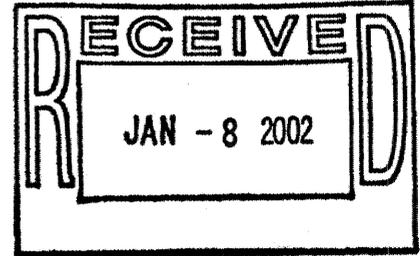


Novartis Consumer Health, Inc.  
560 Morris Avenue  
Summit, NJ 07901-1312

Main Number: 908-598-7600  
Fax: 908-273-2869

January 7, 2002

Office of Nutritional Products  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, Maryland 20740



Dear Sir or Madam:

This correspondence is submitted in accordance with the requirements of Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21CFR101.93. Novartis Consumer Health, Inc. gives notification, that it has, within the last thirty (30) days, started distribution of two (2) flavors of Maalox<sup>®</sup> DS Softchews. The following statements appear on the labels and in the labeling of these calcium carbonate dietary supplements:

- Builds and maintains strong healthy bones
- Relief of occasional heartburn
- May reduce the risk of osteoporosis

These structure/function claims are based on scientific literature, which render the statements substantiated, truthful, and non-misleading. The information submitted herein is complete and accurate.

Novartis Consumer Health, Inc.

A handwritten signature in cursive script that reads 'Jill K. Jarusiewicz'.

Jill K. Jarusiewicz  
Manager, Regulatory Affairs  
enclosures

**Temper Evident Feature:** Do not use if seal under cap is missing or broken.

**WARNINGS:** FOR ADULTS ONLY. Keep out of reach of children. Consult your health professional before using if you are pregnant or nursing a baby. Ask a doctor before use if you are taking a prescription drug. This product may interact with certain prescription drugs. Do not use for relief of heartburn for more than two weeks.

Store at controlled room temperature 20-25°C (68-77°F).

Avoid extreme heat.

Builds and maintains strong healthy bones\*

May reduce the risk of osteoporosis\*

**IMPORTANT INFORMATION ON OSTEOPOROSIS:** Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above 2,000 mg. are not likely to provide any additional benefit.

Questions? call 1-800-452-0951 24 hours a day, 7 days a week.

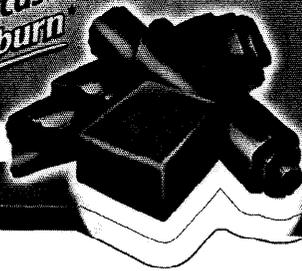
\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Distributed by:  
Novartis Consumer Health, Inc.  
Summit, NJ 07901-1312 ©2007



**New**  
**Maalox<sup>DS</sup>**  
Calcium Supplement  
**Soft Chews**  
Relief of Occasional  
Heartburn

Calcium Rich



**DIRECTIONS:**

Calcium Supplement: Take 1 Chew 3 times a day, preferably with meals.  
For relief of occasional heartburn\*: Take 1 to 2 Chews up to 7 Chews a day.

**Supplement Facts**

Serving Size: 1 Chew

Amount Per Serving	%DV**
Calories	20
Calories from Fat	5
Total Fat	0.6g <1%
Total Carbohydrates	4g 1%
Sugars	3g +
Calcium	400mg 40%
Sodium	15mg <1%

\*\* Percent Daily Values (DV) are based on a 2,000 calorie diet.

+ Daily Value not established.

**Tamper Evident Feature:** Do not use if seal under cap is missing or broken.

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Questions? call 1-800-452-0051 24 hours a day, 7 days a week.

\*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.

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Novartis Consumer Health, Inc.  
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