



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

NOV - 6 2000

Ms. Diane D. McPherson  
Assistant Director, Regulatory Affairs  
SmithKline Beecham Consumer Healthcare  
1500 Littleton Road  
Parsippany, New Jersey 07054-3884

*Rec'd  
NOV 15 2000  
16*

Dear Ms. McPherson:

This is in response to your letter of October 26, 2000 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 SmithKline Beecham Consumer Healthcare is making the claims "Bone health/Osteoporosis" and "Daily source of extra calcium" for its product **TUMS Calcium for Life Bone Health Dietary Supplement**.

The statement "Bone health/Osteoporosis" is a claim of a relationship between calcium and osteoporosis. 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.

975-0163

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Please contact us if you require further assistance.

Sincerely,

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, New Jersey District Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (file, r/f)  
HFS-810  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Nickerson)  
f/t:HFS-811:rjm:10/31/00:docname:73094.adv:disc52

**SB**  
**SmithKline Beecham**  
Consumer Healthcare

October 26, 2000

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

73384  
RECEIVED  
BY: OCT 26 2000

Dear Sir/Madam,

In accordance with 21 CFR 101.93, SmithKline Beecham Consumer Healthcare, Pittsburgh, PA 15205, is hereby giving notice within 30 days of market for a dietary supplement bearing the following statements on the labeling or in the labeling:

**Statements:** Bone health/Osteoporosis (FDA accepted health claim),  
Daily source of extra calcium

**Subject of Claims:** Calcium Carbonate USP

**Name of Supplement:** TUMS Calcium For Life Bone Health Dietary Supplement

The information contained in this notice is complete and accurate and SmithKline Beecham Consumer Healthcare has substantiation that the statements are truthful and not misleading.

Should you have any questions pertaining to this notification, please contact me at (973) 889-2156.

Sincerely,

  
Diane D. McPherson  
Assistant Director, Regulatory Affairs