



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 27 2000

2650 01 JAN -2 P3:57

Ms. Ana Gratie
Quality Assurance Manger
Sunstar Pharmaceutical, Inc.
1300 Abbott Drive
Elgin, Illinois 60123

Dear Ms. Gratie:

This is in response to your letter of November 28, 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 Sunstar Pharmaceutical, Inc. is making the claim "Helps reduce the risk of osteoporosis" for its product **Calcium plus Vitamin D Dr. Health**.

In so far as this statement is based on the relationship solely between the calcium in the product and osteoporosis it 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.

However, if the claimed relationship between the product and osteoporosis is based on the presence of the other dietary ingredients, as well as the calcium, then the claim suggests that this product is intended to treat, cure, prevent, or mitigate a disease. 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. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

978-0163

LET 435

Page 2 - Ms. Ana Gratie

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, Chicago District Compliance, HFR-MW140

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:12/15/00:docname:73602.adv:disc53



SUNSTAR PHARMACEUTICAL, INC.

1300 ABBOTT DRIVE
ELGIN, IL 60123
847-888-1141
FAX: 847-888-1172

Office of Special Nutritionals (HFS-450)
Center of Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 020204

November 28, 2000

Dear Sirs,

Notification of Statement or Dietary Supplement

In accordance with the Code of Federal Registration revised as of April, 1998 §101.93a, we are informing you of the following:

i) The name and address of the manufacturer of the dietary supplement that bears the statement.

Company Name: Sunstar Pharmaceutical, Inc.
Registered Address: 1300 Abbott Drive,
Elgin, IL 60123

ii) The text of the statement that is being made:

Helps reduce the risk of osteoporosis.

iii) The name of the dietary ingredients that are the subject of the statement:

Calcium
Vitamin D

iv) The name of the dietary supplement including brand name:

Calcium plus Vitamin D
Dr. Health

Respectfully,

Sunstar Pharmaceutical, Inc.

By:

Ana Gratie, Quality Assurance Manager
Sunstar Pharmaceutical, Inc.

73602