



JUL 22 2002

4671 02 03-0 0376

Mr. Frank D'Amelio, Jr.
President
Nature's Answer
75 Commerce Drive
Hauppauge, New York 11788

Dear Mr. D'Amelio:

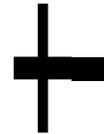
This is in response to your letter of June 17, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Nature's Answer is making the claim "May Reduce Risk of Osteoporosis" for its product **Calcium Crystals Plus™**.

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,

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



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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 York District Compliance, HFR-NE140



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BY: _____

June 17, 2002

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

NOTIFICATION OF STATEMENT(S)
OF NUTRITIONAL SUPPORT

This notification is filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (FDC Act), 21 U.S.C. Section 343(r)(6).

Name of Dietary Supplement: Calcium Crystals Plus™
Statement of Nutritional Support: May Reduce **Risk** of Osteoporosis

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement(s) is (are) truthful and not misleading.

By _____
Frank D'Amelio Jr.
President

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