



MAR 19 2001

Mr. Ira Goldberg
President
Horizon Nutraceuticals
P.O. Box 1806
Santa Cruz, California 9506 1

Dear Mr. Goldberg:

This is in response to your letter of December 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 Horizon Nutraceuticals is making the **claim** "...help maintain and support a healthy) skeletal system, especially during the menopausal years when bone loss increases" for its product **Calcium with Ostivone®**.

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-3 10, 7520 Standish Place, Rockville; Maryland 20855.

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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, Los Angeles District Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-605

HFV-228 (Benz)

GCF- 1 (Nickerson)

f/t:HFS-811:rjm:3/13/00:docname:74399.adv:disc54

Horizon Nutraceuticals
P.O. Box 1806
Santa Cruz, CA 95061

December 28, 2000

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

JAN - 8 2001

RE: Notification of Nutritional **Support** Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of **Calcium with Ostivone®**, a dietary supplement. Horizon® is the manufacturer of **Calcium with Ostivone®**.

Statements being made in the labeling of **Calcium with Ostivone®**:

(I) Calcium with **Ostivone®** combines clinical amounts of ipriflavone with three highly absorbable forms of calcium. It can help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases.)

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Horizon possesses substantiation that the statements are truthful and not misleading.


Ira L. Goldberg
President, Horizon Nutraceuticals

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