



MAY - 5 2001 2 01 MAY 15 P2:30

Mr. Dennis M. Gronek
Gronek & Armstrong
98th Floor - Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606

Dear Mr. Gronek:

This is in response to your letter of April 12, 2001 to the Food and Drug Administration (FDA) on behalf of Horizon Nutraceuticals, Santa Cruz, California. Your letter is in response to our letter dated March 19, 2001 concerning a submission made by Horizon Nutraceuticals pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for its product **Calcium with Ostivone®**. In your letter, you asserted that the claim that we identified as a disease claim or health claim, that is the claim "...help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases," is an appropriate structure or function claim.

We disagree that the claim "...help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases" is a structure or function claim. In the January 6, 2001 Federal Register (65 FR 1000 at 1018) FDA stated that a claim to "maintain normal bone density in post-menopausal women" is a disease claim because post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass. The claim that your client is making, namely "maintain and support a healthy skeletal system" in the "menopausal years when bone loss increases" clearly implies that the product is intended to prevent loss of bone mass that occurs in women as a consequence of menopause and is not materially different in meaning than the claim used as an example of a disease claim in the January 6, 2001 final rule.

For this reason, we are not persuaded that the conclusion expressed in our March 19, 2001 letter is incorrect and we stand by our original determination that the claim proposed by your client in their original submission is a health claim or a disease claim that subjects its product to regulation under the drug provisions of the Act.

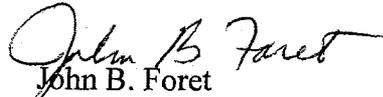
97S 0163

LET 491

Page 2 - Mr. Dennis Gronek

Please contact us if we may be of 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, HFD300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-SE240

Mr. Ira Goldberg

President

Horizon Nutraceuticals

PO Box 1806

Santa Cruz, California 95061

Page 3 - Mr. Dennis Gronek

cc:

HFA-224 (w/incoming)

HFA-305 (docket 973-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-8 10 (Foret)

HFS-8 11 (file)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

r/d:HFS-8 11:RMoore:4/25/01

f/t:HFS-8 11:75504.adv:disc56

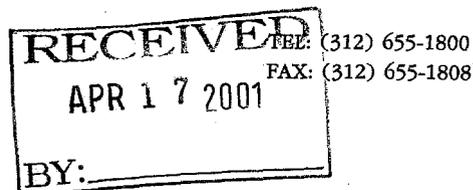
GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR - SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

DENNIS M. GRONEK
ROBERT E. ARMSTRONG
PAUL J. WISNIEWSKI
DEBORAH L. RUSS
JACQUELINE P. KULER

25504



April 12, 2001

John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, DC 20204

Re: Calcium with Ostivone® Courtesy Letter

Dear Mr. Foret:

This firm represents Horizon Nutraceuticals, Santa Cruz, California. Our client requested that we respond to your March 19, 2001 Courtesy Letter concerning claims made for its Calcium with Ostivone® product.

In your letter you object to the claim ". . .help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases." You assert that this statement is an unauthorized health claim. We disagree that this is a health claim and maintain that it is a structure/function claim subject to 21 U.S.C. §343(r)(6).

According to section 403(r)(1)(B) of the Federal Food, Drug and Cosmetic Act ("FDA Act") a health claim is defined as one which "characterizes the relationship of any nutrient to a disease or a health-related condition." The claim submitted by our client does not discuss any disease or health-related condition but merely describes the role of the product in helping to maintain and support a healthy skeletal system.

Osteoporosis is a disease characterized by low bone mass, where the internal structure of the bone has been eroded to the extent that even slight trauma will cause the bone to fracture easily (56 FR 60690). Thus, osteoporosis only exists when bone mass has deteriorated to the extent that internal structure of the bone is eroded thereby easily causing fractures. This is distinguishable from the normal changes which occur in bone mass strength that are natural consequences of the aging process. The FDA acknowledges that all persons

lose bone with age (21 CFR §101.72). However, not all persons develop osteoporosis.

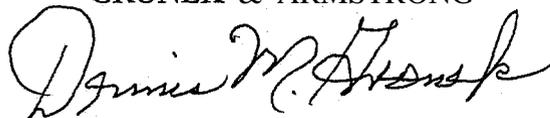
Starting at about 45 years of age, bone loss occurs at a similar rate for both men and women. Prior to and after menopause, women lose bone at a faster rate, then men, but eventually return to the same rate of bone loss as men. Thus, all persons lose bone with age and this loss of bone mass is neither a disease nor a health-related condition.

The statement "...help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases" does not **claim** a relationship between any specific ingredient, calcium or otherwise, and osteoporosis. The claim for this product does not mention osteoporosis nor does it imply that this product will reduce the risk of that disease. Rather the claim refers to maintaining and supporting a healthy skeletal system and the biological fact that bone **loss** increases during the menopausal years. These statements refer to the normal physiological process of bone loss and not to the disease osteoporosis or any health related condition. Accordingly, the statement is not a health claim subject to **21** USC 343(r)(1)(B).

We respectfully request that the Courtesy Letter of March 19, 2001 directed to our client be immediately retracted and an appropriate correspondence acknowledging the propriety of this claim reported for the Calcium with **Ostivone®** product be directed to the undersigned at your earliest convenience.

We look forward to your response to this communication. If you have any questions or desire additional information contact me immediately.

Sincerely,
GRONEK & ARMSTRONG

A handwritten signature in black ink, appearing to read "Dennis M. Gronek", written in a cursive style.

Dennis M. Gronek