



7553 '04 JAN -7 P149

Dale P. DeVore, Ph.D.
Scientific Director
Membrell, LLC
3535 South Garrison Avenue
Carthage, Missouri 64836

DEC 23 2003

Dear Dr. DeVore:

This is in response to your letter of November 10, 2003 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 Membrell, LLC is making the claim "Adequate calcium in a healthy diet along with regular exercise helps build and maintain good bone health and may also reduce the risk of osteoporosis later in life, especially for teens and young adult women" for its product Calcium & Magnesium-Calcium from Eggshells with Vitamin D.

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 yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975 0163

LET 738

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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, Kansas City District Compliance, HFR-SW340

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cc:

all w/copy incoming

HFA-224

HFA-305 (docket 97S-0163)

HFS-800 (file)

HFS-810

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFS-607

HFV-228 (Benz)

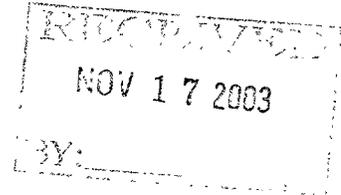
GCF-1 (Nickerson)

f/t:HFS-811:rjm:11/26/03:docname:86525.adv:disc80



November 10, 2003

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



Re: Notification of Dietary Supplement Labeling for
Calcium & Magnesium-Calcium from Eggshells with Vitamin D

To Whom It May Concern:

Please find enclosed one original and two copies of our Notification for Dietary Supplements for Calcium & Magnesium-Calcium from Eggshells with Vitamin D. This notification is submitted in compliance with Section 101.93 of 21 CFR Part 101-Food Labeling; Notification Procedures for Statements on Dietary Supplements, Final Rule.

Please forward correspondence to the following:

Dale P. DeVore, Ph.D.
Scientific Director
Membrell, LLC
3535 S. Garrison Avenue
Carthage, MO 64836 USA

Thank you,
Dale P. DeVore
Dale P. DeVore, Ph.D.

86525

**Notification of Dietary Supplement
Calcium & Magnesium-
Calcium from Eggshells with
Vitamin D**

NOV 17 2003

**Manufacturer/
Distributor:** Membrell, LLC
3535 South Garrison Avenue
Carthage, MO 64836 USA
Phone: 417-358-0024

Text of Statement: "Adequate calcium in a healthy diet along with regular exercise helps build and maintain good bone health and may also reduce the risk of osteoporosis later in life, especially for teens and young adult women."

"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Name of Dietary Supplement: Calcium & Magnesium-Calcium from Eggshells with Vitamin D

Product Label: Enclosed

I certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Signed by: Dale P. DeVore

Title: Scientific Director

Dale P. DeVore
Printed Name

Date: 10 November 2003

