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Mr. Edgardo C. Schirmer
Vice President
MED 2000, Inc.
P.O. Box 21165
1901 Central Drive
Suite 608
Bedford, Texas 76021-8655

Dear Mr. Schirmer:

This is in response to your letter of June 4, 2001 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 MED 2000, Inc. is making the following claim, among others, for the product **VitalOne™ Complete for Women**:

“Provides 100% of the RDA for calcium to reduce the risk of osteoporosis.”

This statement is a claim of a relationship between calcium and osteoporosis. 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.

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Please contact us if you require further assistance.

Sincerely,

for Robert J. Moore

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, Dallas District Compliance, HFR-SW140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

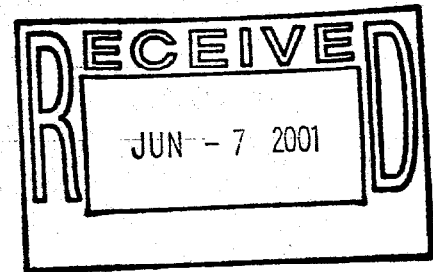
GCF-1 (Nickerson)

f/t:HFS-811:rjm:6/11/01:docname:76281.adv:disc58

MED
2000

June 4, 2001

Food and Drug Administration
Office of Special Nutritionals (HFS-45)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S.C.343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that MED2000, Inc., 1901 Central Drive, Suite 608, Bedford, TX 76021 within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

TEXT OF CLAIM:

- "Provides 100% of the RDA for calcium to reduce the risk of osteoporosis"**
- "Calcium citrate is one of the most biologically active forms of calcium on the market"**
- "Supports a healthy immune system"**
- "Supports cognitive function"**
- "Supports a healthy cardiovascular system"**

NAME OF PRODUCT: VitalOne™ Complete for Women

The undersigned certifies that the information contained in this notice is complete and accurate and that MED2000, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink that reads "Ed Schirmer".

Edgardo C. Schirmer
Vice President

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