



Memorandum

Date: ~~_____~~ **JUL 15 2004**
From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

Subject of the Notification: Cholecalciferol (Vitamin D₃)
Firm: BTR Group, Inc.
Date Received by FDA: 4/14/2004
90-Day Date: 7/13/2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Tanya Jackson, ID5

95S-0316

RPT241



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

James Grote, M.D.
BTR Group, Incorporated
147 Lashmett Avenue
Pittsfield, Illinois 62323

JUN 28 2004

Dear Dr. Grote:

This is to inform you that the notification, dated April 6, 2004, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on April 14, 2004. Your notification concerns the substance cholecalciferol (vitamin D3), that you intend to market as a dietary supplement in your product, "Maximum D3".

According to your notification, you intend to market the dietary supplement, "Maximum D3", in tablet form. Your dietary supplement, "Maximum D3", will contain 10,000 IU or 0.25 mg of cholecalciferol (vitamin D3) per tablet. You state that "the recommended dose is one tablet weekly for adults" and the product will be labeled "as not intended for children, pregnant women, or persons with kidney disease, bone disease, malignancies or calcium disorders."

We note that high doses of vitamin D₃ can cause toxic effects in animals and humans.¹ As the manufacturer/distributor, you are responsible for the safety of your product, "Maximum D3", including the requirement to disclose any consequences that may devolve from the uses of your product as recommended or suggested on the label. Although the Act does not prescribe any specific statements concerning adverse reactions or contraindications that dietary supplements must carry, dietary supplement labeling, like the labeling of all other FDA-regulated products, is required to include all information that is material in light of consequences that may result from the use of the product or representations made about it (see sections 403(a)(1) and 201(n) of the Act).

In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, you must not introduce or deliver for

¹ Klaassen, Curtis D., (ed.): Casarett & Doull's TOXICOLOGY The Basic Science Of Poisons, 6th edition, McGraw-Hill, New York.

introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing cholecalciferol (vitamin D3), if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of March 8, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

Should you have any questions concerning this matter, please contact Dr. Linda S. Pellicore at (301) 436-2375.

Sincerely yours,



for

Susan J. Walker, M.D.

Director

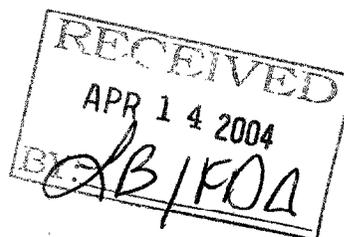
Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition



147 Lashmett
Pittsfield, Il.62363
April 6, 2004

Office of Nutritional Products, Labeling and Dietary Supplements
(HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Gentlepersons:

BTR Group, Inc is submitting a pre-market notification to the FDA pursuant to the Code of Federal Regulations, 21CFR190.6. This application is to notify the Center for Food Safety and Applied Nutrition of the intention of BTR Group to contract manufacture and Market the product **Maximum D3** which contains vitamin D3 (cholecalciferol).

Enclosed are three copies of the application and references.

Yours truly,

James Grote, MD
President
217-285-5170 (voice)
217-285-6188 (fax)
grotejames@hotmail.com

Maximum D3

April 6, 2004

1) BTR Group, Inc. 147 Lashmett Pittsfield, Il. 62363 will contract manufacture the product from Opti-Med CR Labs, Inc. 120 E. Third St. Seymour, In. 47274 (The source of the raw material will be Roche.)

2) The sole active ingredient in **Maximum D3** is vitamin D3 -- cholecalciferol.

3) Cholecalciferol is a fat soluble pro-hormone formed in human skin after exposure to sunlight. It plays a major role in calcium homeostasis, and thus influences bone and muscle function.

i) The intended amount of cholecalciferol in **Maximum D3** is 10,000 IU or 0.25mg per tablet (supplied at retail in blister packs to emphasize single tablet dosing).

ii) The recommended dose is one tablet weekly for adults.

The product will be labeled as **not** intended for children, pregnant women, or persons with kidney disease, bone disease, malignancies or calcium disorders.

The product will be claimed to play an important role in the maintenance of bone health and strength, particularly in persons not regularly exposed to sun light.

4) Historically recommended doses of D3 are based on the prevention of rickets or osteomalacia and are not adequate to prevent osteoporosis or hyperparathyroidism. ^{1, 2, 3} The proposed dosing of **Maximum D3** is thought to be conservative and safe. It is at the lower range of estimates of daily D3 production following exposure to sunlight and within dosage ranges of several studies that have demonstrated long term safety, one using this as a daily dose. ^{3, 4, 5, 6}

References

1) Vieth and Fraser, Canadian Medical Association Journal June 11, 2002; 166 (12)

2) Need, *et al* American Journal of Clinical Nutrition 2000; 71:1577-81

3) Vieth American Journal of Clinical Nutrition 1999;69:842-56

4) Heaney American Journal of Clinical Nutrition 2003;77:204-210

5) Vieth, *et al* American Journal of Clinical Nutrition 2001;73:288-94

6) Trivedi, *et al* British Medical Journal Vol. 326 1 March 2003

James A. Grote, MD



FDAD3APP4_14_04clarification

147 Lashmett
Pittsfield, IL 62363
April 14, 2004

ATTENTION VICKEY LUTWAK

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

1-301-436-2636

Gentlepersons:

RE: REQUEST FOR CLARIFICATION

The new dietary ingredient is MAXIMUM D3.

Yours truly,



James Grote, MD
President
217-285-5170 (voice)
217-285-6188 (fax)
grotejames@hotmail.com