DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

JUL 15 2001

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Holly M. Bayne
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005-5929

Dear Ms. Bayne:

This letter is in response to your letter to the Food and Drug Administration (FDA) dated December 15, 2000. In your letter, you request on behalf of your client, Van Drunen Farms/VDF FutureCeuticals, that your client's new dietary ingredient notification for Glucose Metabolism Modulator (GMM), a malted barley extract, be withdrawn from the docket.

As you are aware, on September 6, 2000, FDA received your client's submission for a new dietary ingredient, which was identified as GMM and described as an extract from the barley plant (*Poaceae, Hordeum vulgare)*. FDA responded to this submission with a letter, dated November 20, 2000. We advised your client of our conclusion that, as represented in the submission, GMM is a drug under 21 U.S.C. 321(g)(1)(B) because it is intended as treatment for non-insulin dependent diabetes mellitus. In addition, the agency found that, even if GMM were a dietary ingredient, the information in the submission did not provide an adequate basis to conclude that GMM, when used under the recommended or suggested conditions of use in the labeling of the product, will reasonably be expected to be safe. This exchange of information between your client and FDA is filed in Docket No. 955-0316.

In your December 15, 2000 letter, you assert that your client erred in submitting a new dietary ingredient notification because GMM is not a new dietary ingredient within the meaning of 21 U.S.C. 350b(c). You contend that the substance in question was marketed as a dietary ingredient prior to October 15, 1994. Further, you argue that GMM, an extract from malted barley, is exempt from the requirement of premarket notification to FDA because barley and malted barley have been widely consumed for food and because your client's extraction process does not chemically alter the barley. For the reasons discussed below, FDA disagrees that you have provided sufficient documentation to establish that GMM was marketed as a dietary ingredient prior to October 15, 1994. Furthermore, we find your arguments under 21 U.S.C. 350b(a)(1) to be unpersuasive.

See RPT84

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The information you presented is not sufficient to support your contention that GMM was marketed as a dietary supplement in the United States prior to October 15, 1994.

We have carefully reviewed the information contained in your letter and find that you have not provided sufficient documentation that GMM, an extract from malted barley, was marketed prior to October 15, 1994. 21 U.S.C. 350b(c) provides that the term "new dietary ingredient" does not include any dietary ingredient that was marketed in the United States before October 15, 1994. In support of your contention that GMM was marketed prior to October 15, 1994, you cite *Herbs of Commerce*, American Herbal Products Association (1992), pp. 8, 36. However, we note that *Herbs of Commerce* lists two species of barley, *Hordeum Vulgare* and *Poacea*, but no extracts of either species. Even if extract of barley were listed in *Herbs of Commerce*, its listing in this publication prior to October 15, 1994, does not establish that extract of barley was marketed as a dietary ingredient before that date, only that extract of barley was known to serve some commercial purpose at the time of publication. By its own terms, *Herbs of Commerce* sets forth only nomenclature for various commercial substances, some of which are used, for example, in cleansing agents and drugs. *Herbs of Commerce* does not purport to list substances used as dietary ingredients. See *Herbs of Commerce*, p. VII.

You also state that barley, barley malt extract, and malt and barley extract are listed in both the "Old Dietary Ingredient List, Utah Natural Products Alliance" (Sept. 1999) and "CRN List of Dietary Ingredients 'Grandfathered' Under DSHEA," Council for Responsible Nutrition (Sept. 1998). Although FDA has tried to acquire copies of these publications, we have been unable to obtain them. As a result, we are unable to determine what criteria were used by these trade associations to identify ingredients marketed prior to October 15, 1994. To establish that GMM is not a new dietary ingredient, you must present evidence showing that GMM, or a substance chemically identical to GMM, was actually marketed as a dietary ingredient in the United States before October 15, 1994. Although reference to a publication listing a substance chemically identical to GMM as having been marketed prior to October 15, 1994, might buttress a claim that GMM is not a new dietary ingredient, the inclusion of such a substance in one or more of these published lists does not, by itself, suffice to show that the substance is not a new dietary ingredient. You also need to demonstrate that the listing of a substance chemically identical to GMM as an "old" dietary ingredient in the publication or publications at issue is founded on accurate and reliable evidence sufficient to support a finding that GMM was marketed as a dietary ingredient prior to October 15, 1994. In the alternative, you could submit independent documentation that GMM is not a new dietary ingredient, such as an

invoice, a bill of lading, or a product label establishing that a substance chemically identical to GMM was marketed as a dietary ingredient prior to October 15, 1994.

The information you presented is not sufficient to support your contention that GMM is exempt from FDA premarket notification.

In a second line of argument, you contend that GMM, an extract from malted barley, is exempt from FDA premarket notification because barley and malted barley have been widely consumed for food and because your client's extraction process does not chemically alter the barley. Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new ingredient is reasonably expected to be safe. You maintain that the source material from which GMM is extracted, barley or malted barley, is present in the food supply and is not chemically altered to produce GMM. Based on these grounds, you conclude that GMM is not subject to the premarket notification requirement in 21 U.S.C. 350b(a).

The evidence you present to support this conclusion is inadequate, however. You present no documentation that GMM, as opposed to the source material for GMM, is present in the food supply "as an article used for food," i.e., as a food or as an ingredient in food. The mere incidental presence of a substance as an inherent component of articles used for food does not establish that the substance itself is "an article used for food." Therefore, the information you have provided is not sufficient to support your contention that GMM is not subject to the premarket notification requirement under 21 U.S.C. 350b(a).

For the reasons stated above, the agency cannot grant your request to withdraw the GMM notification. Should your client present persuasive evidence to support your contention that GMM was marketed as a dietary ingredient in the United States prior to October 15, 1994, or that GMM has been present in the food supply as an article used for food in a form in which the substance has not been chemically altered, FDA would consider formally noting in the file displayed at docket No. 95S-0136 that GMM is not subject to the pre-market notification requirements under 21 U.S.C. 350b. However, inasmuch as 21 U.S.C. 350b(a) requires that we place information provided under subparagraph (2) on public display, we will not physically remove the premarket notification from the docket even if your client presents sufficient evidence to show that the law did not require your client to file such a notification.

The additional information that you have submitted on December 15, 2000 will be filed in docket No. 95S-0316 to supplement the record for the submission.

If your client is able to compile credible scientific support for its conclusion that GMM will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, your client is free to submit a new premarket notification for GMM under 21 U.S.C. § 350b(a)(2). Finally, be advised that, if your client continues to represent that the product is intended as treatment for non-insulin dependent diabetes mellitus, the product will be deemed to be a drug under 21 U.S.C. 321(g)(1)(B).

Should you have any questions concerning this matter, please contact me at (202) 205-4168.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
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December 15, 2000

BY HAND

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Director
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Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-800)
200 C Street, SW
Washington, DC 20204

Re: Van Drunen Farms/VDF FutureCeuticals

Dear Ms. Satchell:

This responds to your November 20, 2000 letter addressed to Mr. Jeff Van Drunen, of Van Drunen Farms/VDF FutureCeuticals ("VDF"), a client of our law firm, concerning a new dietary ingredient notification submitted to the Food and Drug Administration (FDA) for an extract of the barley plant, *Hordeum vulgare*. The notification was submitted in error since the malted barley extract, identified in VDF's notification and your letter by its fanciful name "Glucose Metabolism Modulator" ("GMM"), is not a "new dietary ingredient" within the meaning of section 413(c) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 350b. Thus, GMM may be lawfully sold as a dietary ingredient intended for use in dietary supplements without premarket notification to FDA. Accordingly, on behalf of VDF and for the reasons set forth below, we ask that the new dietary ingredient notification for "GMM (a natural extract from Barley (poaceae, hordeum vulgare)" be withdrawn from the docket.

As you know, under section 413(a) of the FDC Act, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA), the filing of a 75-day premarket notification with FDA is required only for "new dietary ingredients" in dietary supplements that were not marketed in the United States prior to October 15, 1994 or have not been present in the food supply as an article used for food in a form in which the food has not been chemically altered. 21 U.S.C. § 350b(a) (emphasis added). The law expressly defines the term "new dietary ingredient" to mean a "dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(c) (emphasis added).

As defined in section 201(ff) of the FDC Act, a "dietary ingredient" may include "an herb or other botanical" and its "concentrate, metabolite, constituent, [or] extract." 21 U.S.C. § 321(ff)(1)(C), (F). Both the botanical barley (*Hordeum vulgare)* and extracts of barley and malted barley were marketed prior to October 15, 1994. See Herbs of Commerce, American Herbal Products Association (1992) (listing barley, *hordeum vulgare*, and *poaceae*), pp.8, 36; Old Dietary Ingredient List, Utah Natural Products Alliance (Sept.1999) (listing barley, barley malt extract, and malt and barley extract), pp. 4, 20; CRN List of Dietary Ingredients "Grandfathered" Under DSHEA, Council for Responsible Nutrition (Sept. 1998) (listing barley, barley malt extract, and malt and barley extract), pp. 3, 19.

As an "old" or "grandfathered" dietary ingredient, extract of malted barley is not subject to section 413(c) of the FDC Act requiring FDA premarket notification. 21 U.S.C. § 350b(c). Therefore, there was no need for VDF to file a new dietary ingredient notification. VDF – a company unfamiliar with the regulation of dietary supplements – mistakenly believed that it was necessary to file the notification, not understanding that its extract from malted barley is exempt from the premarket notification requirement.

Moreover, an extract from malted barley is also exempt from FDA premarket notification because malted barley extract has "been present in the food supply as an article used for food in a form in which the food has not been chemically altered." 21 U.S.C. § 350b(a)(1). The "Statement of Agreement" constituting the entire legislative history of DSHEA provides that "the term 'chemically altered' does not include the following physical modifications: minor loss of volatile components, dehydration, lyophilization, milling, tincture or solution in water, slurry, powder or solid in suspension." 140 Cong. Rec. H11179 (daily ed. Oct. 6, 1994).

Barley and malted barley have been widely consumed for food and beverage use for centuries. Based on information provided to us from our client concerning the extraction process by which VDF's malted barley extract is produced, the process is within the types of physical modifications that would not render the barley to be deemed "chemically altered" within the meaning of section 413(a) of the FDC Act. 21 U.S.C. § 350b(a). Thus, for this addition reason, VDF did not need to submit a new dietary ingredient notification to FDA for its malted barley extract.

In your November 20 letter, you stated that FDA believes that VDF's dietary ingredient, GMM, is a drug under 21 U.S.C. § 321(g)(1)(B) because "it is intended for treatment of non-insulin dependent diabetes mellitus." As previously indicated, when VDF filed the new dietary ingredient notification with FDA, the company was not well informed as to the legal requirements for marketing dietary supplements, including the types of labeling claims that would appear permissible pursuant to section 403(r)(6) of the FDC Act and FDA regulation. 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93. As recently retained counsel to VDF, we will advise the company as to the types of claims that would appear appropriate for dietary supplement labeling in accordance with section 403(r)(6) and other provisions of the FDC Act and FDA's regulations and enforcement policy.

Again, for the reasons set forth above, we request that FDA withdraw from the docket the new dietary ingredient notification submitted by Mr. Jeff Van Drunen for VDF's extract of malted barley.

Thank you for your consideration. Please contact me if you have any questions.

Sincerely,

Holly M. Bayne

HMB/eam
cc: Mr. Jeff Van Drunen
Van Drunen Farms/VDF FutureCeuticals