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February 25, 2004

Eingang VF
26. Feb. 2004

BY FACSIMILE/CONFIRMATION
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Dr. Manfred Eggersdorfer
Head of R&D Vitamins Division
Director
DSM Nutritional Products
(registered as Roche Vitamins Ltd.)
Building 241/553
CH-4070 Basel
SWITZERLAND

Dear Dr. Eggersdorfer:

This provides our opinion concerning the regulatory status of Epigallochatechin gallate (EGCG), an extract from green tea leaves, as a dietary supplement in the United States. As explained below, we believe that DSM Nutritional Products (registered as Roche Vitamins Ltd.) may market EGCG as a dietary ingredient and dietary supplement without having to first submit to the Food and Drug Administration (FDA) a new dietary ingredient (NDI) notification in accordance with Section 413 of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 350b.

The NDI notification is required for a dietary ingredient that "was not marketed in the United States before October 15, 1994" and 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." FDC Act § 413(a) and (c); 21 U.S.C. § 350b(a) and (c). We understand that green tea extracts naturally containing EGCG were marketed in the U.S. prior to that date. Thus the ingredient has "been present in the food supply" in green tea, apparently without being "chemically altered."

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As evidence that the substance is not regarded as requiring NDI notification, there are several dietary supplement products on the U.S. market that are labeled as containing EGCG, yet no one has submitted an NDI notification to FDA for EGCG. Moreover, it is clear that FDA is aware of these products.

Under the FDC Act, manufacturers are required to notify FDA of all label claims that a dietary supplement will affect the structure or function of humans, within 30 days of the first marketing of the dietary supplement. FDC Act § 403(r)(6); 21 U.S.C. § 343(r)(6). As part of the notification, manufacturers must list all dietary ingredients in the dietary supplement. 21 C.F.R. § 101.93(a)(2)(iii). If FDA objects to these structure/function notifications for any reason, the agency sends a "courtesy" letter informing the notifier of that opinion.

Several manufacturers have notified FDA of structure/function claims they are making for dietary supplements containing EGCG, pursuant to this requirement. Attached are copies of two such letters: Letter from Pharmanex (Feb. 16, 2000) ("The antioxidant catechins EGC and EGCg are two of the most powerful free radical fighters known."); Letter from The Vitamin Shoppe (Nov. 23, 2001) (excerpts of attachment showing structure/function claims for dietary supplements containing Epigallocatechin Gallate). To our knowledge, FDA has not objected to any notifications for structure/function claims for EGCG. Although not as definitive as a specific response would be, the absence of an FDA objection to these notifications strongly suggests that FDA does not believe that an NDI submission is required for EGCG.

Finally, the attached opinion of Dr. Joseph F. Borzelleca, a recognized expert in toxicology and food safety, based on his independent review of the data on the safety of EGCG in TEAVIGO™, clearly establishes that TEAVIGO™ is "reasonably expected to be safe" as labeled. FDC Act § 413(a)(2); 21 U.S.C. § 350b(a)(2). However, it is not necessary to send the data to FDA if the ingredient does not require an NDI submission. Therefore, we recommend that you simply hold this information for possible use in the unlikely event that FDA were to question the status of the ingredient.

Please let us know if you have any questions concerning this matter.

Sincerely,

Paul M. Hyman

PMH/eam
Attachments
3683.013.01