



APR 17 2006

Mr. Michael Farber, MSc, President.
Oral Delivery Technologies
37 Prospect Street
Nutley, New Jersey 07110

Dear Mr. Farber:

This is to inform you that the notification, dated December 28, 2005, that 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 January 13, 2006. Your notification concerned a new dietary supplement consisting of a combination of "25 mg 7ketoDHEA", "25 mg of Hoodia Gordinii 20:1 extract", "25mg citrus aurantium extract", "5 mg pepper extract" and "5 mg of 6,7 dihydroxy bergamottins(grapefruit rind extract)". Your notification does not clearly identify the ingredient(s) that is (are) the subject of the notification, i.e. the "new dietary ingredient(s).

Your notification states that "[t]he 85 mg total of components will be available as a tablet or drink to be consumed up to a maximum of three times a day to increase metabolism and reduce appetite."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing 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 dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b (a) (2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f) (1) (B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Your submission of a notification for a new dietary ingredient makes clear that you have determined that your dietary supplement product contains one or more new dietary ingredients that are subject to the notification process under section 413(a)(2) of the Act. Specifically, you have determined that the dietary supplement does not only contain dietary ingredients which have been present in the food supply as an article used for food in a form which has not been chemically altered. Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification does not comply with the requirements of 21 CFR 190.6 and is incomplete. The following items were not included with your submission: (1) An original and two copies of the notification, (2) The name of your new dietary ingredient(s), (3) the Latin binomial (including the author) of any herb or other botanical when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. In addition, any reference to published information offered in support of the notification shall be accompanied by reprints of photostatic copies of such references.

In addition it is unclear how your ingredient(s) is qualitatively or quantitatively similar to the substances described in the information that you present as evidence of safety for your product, or how that information is relevant to evaluating the safe use of your product under the recommended conditions of use.

FDA is unable to determine whether the scientific studies cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (<http://www.cfsan.fda.gov/~lrd/cfr190-6.html>), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

This letter supersedes the letter dated March 29, 2006.

Your notification will be kept confidential for 90 days after the filing date of January 13, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch 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.

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

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