

Memorandum

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Date: OCT 11 2006

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: Capsinoids (Extracted Oil of Sweet Chili Peppers)
Capsicum annum L.

Firm: Ajinomoto U.S.A., Inc.

Date Received by FDA: 7/19/2006

90-Day Date: 10/17/2006

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.

Victoria Lutwak

19955-0316

RPT 360



Robert G. Bursey, Ph.D.
Ajinomoto U.S.A., Inc.
1120 Connecticut Avenue, N.W., Suite 1010
Washington, District of Columbia 20036-3953

OCT 2 2006

Dear Dr. Bursey:

This is to inform you that the notification, dated July 18, 2006, you submitted pursuant to 21 U.S.C. 3501b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) was received by the Food and Drug Administration (FDA) on July 19, 2006. Your notification concerns the new dietary ingredient "Capsinoids (Extracted Oil of Sweet Chili Peppers)," also called "CH-19 Sweet Extract," that you intend to market in a dietary supplement product called "Capsiate Natura™." According to your notification, "Capsinoids (Extracted Oil of Sweet Chili Peppers)" is derived from *Capsicum annuum* L. chili peppers.

According to your notification, the new dietary ingredient will be in the form of soft gel capsules that will contain 1 mg of "Capsinoids (Extracted Oil of Sweet Chili Peppers)." The recommended conditions of use for "Capsinoids (Extracted Oil of Sweet Chili Peppers)" are to take three 1 mg capsules orally once per day.

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.

FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "Capsinoids (Extracted Oil of Sweet Chili Peppers)" will reasonably be expected to be safe.

Based on the information in your submission, FDA was unable to determine the identity of your new dietary ingredient, "Capsinoids (Extracted Oil of Sweet Chili Peppers)". The extraction process is described in very general terms. The Notification does not include methods of analysis for the any components, active or inactive. The notification does not provide studies with the preparation that will be marketed as a dietary supplement. It is unclear to FDA how "Capsiate Natura™" is qualitatively or quantitatively similar to peppers and thus, it is unclear how information about the safe use of the new dietary ingredient is relevant to an evaluation of conditions of use.

Your notification describes a history of use of chili peppers throughout the world and the estimated current intakes of capsinoids in the U.S. based on per capita chili pepper consumption. However, the recommended intake of the new dietary ingredient (i.e., 3 mg capsinoids/day) is about twice the current estimated daily intake at the 90th percentile of intake by chili pepper eaters. Moreover, it is not possible to calculate the concentration of capsinoids present in the proposed dietary supplement based upon information provided. Your notification does not provide data or other information that supports the safe use of capsinoids at levels significantly higher than those for which there is history of use or exposure to these substances as constituents of food.

Your notification includes results from a 13-week oral toxicity study of "CH-19 Sweet Extract" in rats. According to you notification "CH-19 Sweet Extract" is a synonym for "Capsinoids (Extracted Oil of Sweet Chili Peppers)". However, the information provided from this study raises concerns about cardiac toxicity of "Capsinoids (Extracted Oil of Sweet Chili Peppers)" and was inadequate to allow FDA to evaluate the basis for the safety of your product. For example, there were highly significant, treatment-related increases in the incidence and degree of focal myocarditis in male rats in each test substance group. Based on the safety data and information submitted in your notification, there is insufficient information for the assessment of reasonable safety of "Capsiate Natura™" as a dietary supplement.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Capsinoids (Extracted Oil of Sweet Chili Peppers)," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be 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).

Your notification will be kept confidential for 90 days after the filing date of July 19, 2006. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket 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.

Page -3 - Dr. Robert G. Bursley

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Victoria Lutwak for". The signature is written in a cursive, flowing style.

Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements,
Center for Food Safety and Applied Nutrition