DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: April 12, 2013

From: Fred Hines, Consumer Safety Officer, New Dietary Ingredient Review Team, Division of Dietary Supplement Programs , Office of Nutrition, 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: Inositol stabilized arginine silicate (Trade name: Nitrosigine)

Firm: Nutrition21

Date Received by FDA: January 10, 2013

90-Day Date: April 10, 2013

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 FDA-2013-S-0023 as soon possible since the 90-day date is April 10, 2013. Thank you for your assistance.

Fred A. Hines, DVM, CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

MAR 1 8 2013

James Komorowski, MS, CNS
V.P., Research and Development
Nutrition21
3 Manhattanville Road, Suite 201
Purchase, New York 10577

Dear Mr. Komorowski:

This is to inform you that the notification, dated January 4, 2013, which you submitted pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was received and filed by the Food and Drug Administration (FDA) on January 10, 2013. Additional material was filed on March 4 and March 11, 2012. Your notification concerned the new dietary ingredient that is called "Nitrosigine™, an inositol-stabilized arginine silicate mixture" (or ASI) which is a mixture of the amino acid arginine, the mineral silicate and inositol (a glucose isomer) and that you intend to market in bulk dietary ingredient form to the dietary supplement industry.

According to your notification, you intend to recommend the dietary supplement tablet formulation as providing a maximum level of 337.5, 195, and 217.5 mg of arginine, silicate, and inositol, respectively, as well as a maximum of 45 mg potassium, totaling 795 mg of Nitrosigine per tablet. The recommended serving size is "2 tablets/day" providing a maximum daily consumption of 1,590 mg Nitrosigine. The recommended usage is stated as follows: "[T]he product label will indicate that nitrosigine is recommended for use in adults only, and that the product should not be used by pregnant or lactating women."

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 21 U.S.C. 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.

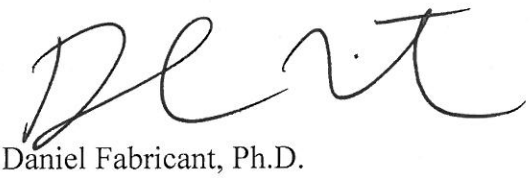
In accordance with 21 CFR 190.6 (c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient 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 ingredients or supplement that contains the new dietary ingredients are safe or are not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredients if they are found to be unsafe, adulterated or misbranded.

Your notification will be kept confidential for 90 days after the filing date of March 11, 2013. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number FDA-2013-S-0023 (formerly docket numbers FDA-1995-S-0039 or 95S-0316) as new dietary ingredient notification report number 786. 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.

If you have any questions concerning this matter please contact Dr. Fred Hines, Consumer Safety Officer, New Dietary Ingredients Review Team, at (240) 402-1756.

Sincerely yours,



Daniel Fabricant, Ph.D.
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