

Memorandum

Received 8/18/06
JS

Date:

AUG 4 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: **"Bacillus Polyfermenticus"**

Firm: Piscium Internationalsl.

Date Received by FDA: May 8, 2006

90-Day Date: August 6, 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 350



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

JUL 19 2006

Mr. John H. Choi, CEO
Piscium International, Inc.
779 Granite Avenue
Langhorne, Pennsylvania 19407

Dear Mr. Choi:

This is to inform you that the notification, dated May 2, 2006, that you submitted as a representative of BINEX Co., Ltd of Busan Korea, 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 May 8, 2006. Additional information was received on May 24, 2006. Your notification concerned the substance that you called "Bacillus Polyfermenticus SCD" that you assert is a new dietary ingredient and that BINEX intends to market in a dietary supplement product to be called "BISCAN®".

Your notification states that "BISCAN®" will be marketed in tablet or capsule form and that [e]ach tablet or capsule of BISCAN® contains 83.35 mg (1.667×10^7 of Bacillus Polyfermenticus SCD live freeze dried lyophilized strain) of Bacillus Polyfermenticus SCD.... The package labeling instructs consumers to take two tablets or capsules in the morning and two in the afternoon and two in the evening for a total of 6 units/day (500mg/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 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.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that "Bacillus Polyfermenticus SCD" will reasonably be expected to be safe.

FDA was unable to establish the identity of "Bacillus Polyfermenticus SCD". Information in your notification describes the organism variously as a unique species of the genus *Bacillus*, as 99.5% similar to *Bacillus subtilis*, and as similar to species from the genus *Lactobacillus* that are found in Kimchi and other fermented foods. Moreover, it is unclear how your ingredient is related to the various strains of "Bacillus Polyfermenticus SCD" described in your notification such as "Bistroot Strain", "Bisroot Strain", "Mutant KD21" and "strain SCD KCCM 10104". In addition, while your notification states that your ingredient is the "live freeze dried lyophilized strain" of "Bacillus Polyfermenticus SCD", it is unclear whether your ingredient consists only of bacterial endospores or if it also includes the culture media in which the organisms were grown.

Because FDA was unable to identify "Bacillus Polyfermenticus SCD" it is not readily apparent whether the ingredient that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear that "Bacillus Polyfermenticus SCD" is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). Therefore, FDA can not determine, at this time, whether your product contains a dietary ingredient(s) that may lawfully be marketed as a dietary supplement.

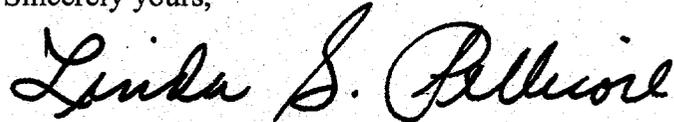
For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Bacillus Polyfermenticus SCD", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product 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 May 8, 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.

Page -3- Mr. John H. Choi

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

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Pellicore". The signature is written in a cursive style with a large, prominent initial "L".

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