



MAY 31 2005

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

Michael W. Kenworthy, President  
Technology Commercialization Corp.  
45 Tudor City Place, Suite 1619  
New York, NY 10017-7611

Dear Mr. Kenworthy:

This is to inform you that the notification you submitted, dated February 7, 2005, 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 February 14, 2005. Your notification concerns the substance that you identify as "Fermented Supernatant or Probiotic Booster", which you intend to market as a new dietary ingredient.

According to the notification, you intend to market your proposed new dietary ingredient "Probiotic Booster" in solution [liquid] form. You state in the notification that "... one tablespoon (or 0.15 ml per kg body weight) of Probiotic Booster should be mixed with yogurt, juice or water in proportion 1:3 to 1:5, and take 2 to 3 times per day after meals." You also state in the notification "For stronger effect, use undiluted. For intensive administration, the dose can be increased to 2 tablespoons (or 0.3 ml per kg body weight) 2 to 3 times per day after meals." You indicate that the labeling for "Probiotic Booster" will contain a warning: "Because of the acidity (high lactate and other organic acids) of undiluted Probiotic Booster, it should not be ingested in undiluted form by people with an ulcer or any intestinal or stomach inflammation. For such people, the Probiotic Booster should be diluted in yogurt (in proportions of 1:5), not acidic juice or water, immediately before consumption."

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.

The Act and the agency's implementing regulations require that the notification contain history of use or other evidence of safety for establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe (21 U.S.C. 305b(a)(2) and 21 CFR 190.6(b)(3)(ii)). Your notification states that you intend to market your proposed new dietary ingredient "Probiotic Booster" in solution [liquid] form. You state in the notification that "... one tablespoon (or 0.15 ml per kg body weight) of Probiotic Booster should be mixed with yogurt, juice or water in proportion 1:3 to 1:5, and take 2 to 3 times per day after meals." However, your notification also states "for stronger effect, use undiluted." In addition, your notification states that your dietary supplement product may be used for "intensive administration" by increasing the dosage to 2 tablespoons taken 2 or 3 times per day. The recommended conditions of use as stated in your notification are unclear because your notification does not contain information describing the various conditions which require a "stronger effect" or "intensive administration".

Nevertheless, 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 a dietary supplement containing "Probiotic Booster" will reasonably be expected to be safe.

Your notification describes a fermentation process that combines plant, animal and live bacterial ingredients. The notification contains lists of potential ingredients, but not the actual ingredients that will be used. The description of the ingredients, the manufacturing process, and the product that is the result of that process are each so unclear that it is impossible to determine the identity of "Probiotic Booster" or evaluate the safety of a product that is or contains "Probiotic booster".

In addition, although the notification contains photocopies of 13 articles from scientific and medical journals, the articles do not specifically pertain to the proposed dietary ingredient, "Probiotic Booster". The 13 articles describe the safety and efficacy of probiotic ingredients in general or the safety and efficacy of specific bacterial species in specific foods. However, none of the articles appear to contain information from studies of preparations that are chemically and/or microbiologically similar to "Probiotic Booster". Therefore, it is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your "Probiotic Booster" or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

Moreover, the notification does not present history of use or other evidence of safety for any material that is similar to Probiotic Booster.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Probiotic Booster" 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 February 14, 2005. 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.

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

Sincerely yours,

A handwritten signature in black ink, appearing to be 'S. Walker', written in a cursive style.

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