



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

Mr. David Wales
American BioSciences Inc.
560 Bradley Parkway, #4
Blauvelt, NY 10913

JAN 11 2005

Dear Mr. Wales:

This is to inform you that the notification, dated October 27, 2004, 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)) and revised on November 17, 2004 was filed by the Food and Drug Administration (FDA) on November 3, 2004. Your notification concerns the substance "fermented wheat germ", prepared from *Triticum aestivum* L. subsp *aestivum* and *Saccharomyces cerevisiae* that you intend to market as a new dietary ingredient contained in a dietary supplement product that you call "Avemar".

According to the notification, you intend to market your new dietary ingredient "fermented wheat germ" as part of your dietary supplement product, "Avemar", which will be marketed in microgranulated form. You indicate that a "9-g dose of Avemar, containing 5.3 g of the NDI fermented wheat germ, is to be taken once per day with the Avemar microgranules dissolved in 150 mL water." According to your notification, "[t]he label will recommend that Avemar not be taken by children or by women who are pregnant or breast feeding. It should not be taken by those who have undergone organ or tissue transplants, or those who suffer from bleeding erosions or bleeding ulcers of the gastrointestinal tract, enteritis, colitis, or malabsorption syndrome. Patients taking prescription medications should consult with their doctors before use. The label will also state prominently that the product contains gluten."

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 concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing “fermented wheat germ” will reasonably be expected to be safe.

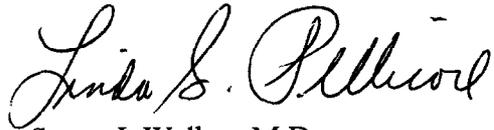
Your notification fails to clearly identify the new dietary ingredient that you call “fermented wheat germ” because the notification did not include an adequate description of the composition and manufacturing process for your new dietary ingredient, “fermented wheat germ”. For example, the description of the manufacturing method in section 4C of your notification does not contain a clear and complete list of the ingredients used to make “fermented wheat germ”. In addition, the description of the manufacturing method in that section does not appear to FDA to be consistent with the description in section 4D(2) of the notification. Furthermore, the method of manufacture does not describe how the indicated levels of 2,6-dimethoxy-p-benzoquinone (DMBQ) are achieved. Furthermore, the specifications provided in section 4A(2) are not consistent with DMBQ levels listed in the stability samples described in 4A(3).

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the “Avemar” product, 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 November 3, 2004. 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,



for,

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