



Food and Drug Administration  
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Diane B. McColl  
Hyman, Phelps and McNamara, P.C.  
700 Thirteenth Street, N.W.  
Suite 1200  
Washington, D.C. 20005-5929

MAR 1 2005

Dear Ms. McColl:

This is to inform you that the notification, dated December 14, 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)) was filed by the Food and Drug Administration (FDA) on December 15, 2004. Your notification concerns the substance "Kakadu Plum Concentrate", prepared from *Terminalia ferdinandiana* Exell, that you intend to market as a new dietary ingredient.

According to the notification, Access Business Group L.L.C. (ABG) will supply this new dietary ingredient to dietary supplement manufacturers for use in dietary supplements. You state that "such products would reasonably be expected to deliver 100-800 mg 'Kakadu Plum Concentrate' per day, providing a daily intake of 15 mg to 360 mg Vitamin C under the ordinary conditions of intended use of the supplement."

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 "Kakadu Plum Concentrate" will reasonably be expected to be safe.

The history of use evidence presented primarily relates to traditional use of the Kakadu Plum fruit rather than your "Kakadu Plum Concentrate". It is unclear to us how the history of use information you submitted in your notification relates to the "Kakadu Plum Concentrate" that you intend to market as a new dietary ingredient. In addition, the relationship between the composition of the materials used in the various test reports and the composition of the substance you call "Kakadu Plum Concentrate" is unclear. Therefore, it is unclear to us how the substances referred to in the information submitted relate qualitatively and quantitatively to the concentrate you plan to market.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your new dietary ingredient, "Kakadu Plum Concentrate", 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 December 15, 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