



Mitchell L. Tate, CEO  
The Center for Lifestyle Disease  
PO Box 1487  
Surprise, Arizona 85378

OCT 3 2006

Dear Mr. Tate:

This is to inform you that the notification, dated July 18, 2006, 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 July 25, 2006. Additional information dated July 27 was received on August 1, 2006. Your notification concerned the substance that you called "Absolbotani" that you intend to market as a new dietary ingredient.

According to your notification, "Absolbotani" will be marketed in a liquid dietary supplement containing "natural or artificial orange flavor, vitamin C, sweetener, mild saline, and Absolbotani". The level of "Absolbotani" in the dietary supplement product "will be 1 part Absolbotani to 2000 parts the remaining ingredients or .05% presence of Absolbotani." The notification states that the serving levels will be 18 drops for adults (12 servings per bottle), 12 drops for "children & under 100 lbs", and 4-7 drops for toddlers under 2 years. Further conditions of use include directions to "[s]hake bottle gently and [d]rop appropriate number of drops directly into the mouth or into juice or water and swallow. Repeat 3-4 times per day until bottle is empty. It is important to check with your health care provider before taking dietary supplements." In addition, your notification states that "[o]n average adults would use the product (complete 12 doses) once to twice monthly. During winter months, the frequency of use may double or triple in a month's time."

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 21U.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 21U.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.

Your notification concerning "Absolbotani" does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your notification identifies "Absolbotani" only as being "made by combining a propriety aqueous extract and a propriety alcohol extract from 3 different plants." Your notification fails to provide the name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical. The notification also does not describe the levels of the unnamed botanical extracts within "Absolbotani".

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Absolbotani", 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 July 25, 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.

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

Sincerely yours,



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