



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

Mr. Lorens Safavi
General Manager
Antanais Corp (Suisse) SA
P.O. Box 558
1211 Geneva 17
Switzerland

NOV 30 2004

Dear Mr. Safavi:

This is to inform you that the notification, dated August 29, 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 September 16, 2004. Your notification concerns the substance "Argan Oil", extracted from *Argania spinosa* (L.) Skeels, that you intend to market as a new dietary ingredient.

According to the notification, you intend to market your new dietary ingredient "Argan Oil" in softgel capsules, each containing 300 mg of "Argan Oil". You indicate that the level of use is expected to be 1 to 2 softgel capsules per day for adults and that the product is not to be used by children under 12 years of age.

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 "Argan Oil" will reasonably be expected to be safe.

Your notification fails to clearly identify the new dietary ingredient that you call "Argan Oil". The notification fails to clearly identify the composition and manufacturing process for your new dietary ingredient, "Argan Oil".

None of the material included with the notification appears to be specifically related to your new dietary ingredient, or any product containing that ingredient, that are the subject of this notification. Your notification contained newspaper articles and other material that provided general descriptions of a variety of products called argan oil that are sold for or used in food. It is not evident how these products are qualitatively or quantitatively similar to your new dietary ingredient, "Argan Oil", or how these materials are relevant to evaluating the safe use of your new dietary ingredient under the conditions of use recommended or suggested in the labeling of your dietary supplement product.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the "Argan Oil" 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 September 16, 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,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

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