



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

NOV 10 2004

Mr. Steven Shapiro
Ms. Vanessa Riviere
Ullman, Shapiro & Ullman, LLP
299 Broadway, Suite 1700
New York, NY 10007

Dear Mr. Shapiro and Ms. Riviere:

This is to inform you that the notification you submitted, dated August 24, 2004, on behalf of your client, Gencor Pacific, Inc. (Gencor), 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 August 31, 2004. Your notification concerns the substance called "*Caralluma fimbriata* extract" an extract of the plant "*Caralluma fimbriata* Wall." that you intend to market as a new dietary ingredient.

The notification informs FDA that Gencor "intends to market "*Caralluma fimbriata* extract" in powdered form, with a recommended dose of 500 mg twice per day." The notification further states that "the final product containing the new dietary ingredient will be available to consumers in various forms including capsule, softgel, tablet or liquid form."

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 "*Caralluma fimbriata* extract" will reasonably be expected to be safe.

It is unclear to FDA how the history of use information you submitted in your notification regarding the plant *Caralluma fimbriata*, relates to the "*Caralluma fimbriata* extract" that you intend to market as a new dietary ingredient. According to the notification, 100 g of raw plant is equivalent to 1 g of the new dietary ingredient, but this claim is not substantiated.

Furthermore, the relationship between the composition of the materials used in the various test reports and the composition of the substance you call "*Caralluma fimbriata* extract" is unclear. For example, you state that "*Caralluma fimbriata* extract" is dried plant material, but you do not provide specifications of purity, limits on potential contaminants or a compositional analysis of your product. In the notification, there were discrepancies in the descriptions of the solvents used in the "Manufacturing Process of *Caralluma fimbriata* Extract" described in (Exhibit 3.), "Method of Preparation of *Caralluma fimbriata* Extract" (Exhibit 5.) and "Material and Methods" section of a research paper entitled "*Caralluma fimbriata* in the Treatment of Obesity" (Exhibit 7.).

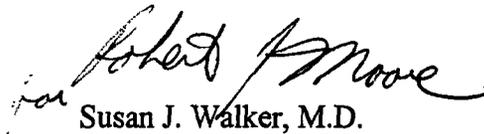
In addition, the use of hexane was described in the extraction process in Exhibit 3., but the notification lacked information regarding the testing for residual hexane and a specification for hexane removal from final product. FDA notes that hexane is not a United States Pharmacopeia approved food solvent.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "*Caralluma fimbriata* extract", 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 August 31, 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 cursive script, appearing to read "Susan J. Walker".

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