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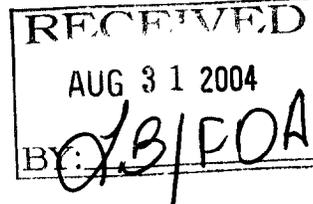
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August 24, 2004

VIA FEDERAL EXPRESS

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: New Dietary Ingredient Notification for *Caralluma Fimbriata* Extract

Dear Sir/Madame,

Pursuant to 21 CFR §190.6, please be advised that Gencor Pacific, Inc. ("Gencor") of Virginia Beach, VA is hereby providing you with notification of its intent to market a New Dietary Ingredient, namely *Caralluma fimbriata* extract. Gencor will commence marketing of its *Caralluma fimbriata* extract 75 days after acknowledgment of your receipt of this notification, unless otherwise instructed by your agency. Enclosed with this original document are two additional copies of the Gencor submission and the attachments thereto.

Based upon the following, Gencor respectfully submits that there are no safety issues relating to its intended marketing of *Caralluma fimbriata*:

1. Gencor Pacific is a supplier of dietary ingredients and botanical extracts. The company is located at 10025 Circle New Drive, Austin, Texas 78733.¹ The founders and directors of Gencor Pacific have been in the pharmaceutical and natural products industry for over 20 years.

¹ Gencor Pacific also has offices at 5721 Bayside Road, Suite B, Virginia Beach, VA 23455.

2. The new dietary ingredient is *Caralluma fimbriata* (Wall, 1829) extract and is expected to be used with a structure/function statement related to appetite suppression/weight loss. *Caralluma fimbriata* is an edible cactus from the *Asclepiadiceae* family and has been a part of the daily diets of India natives for centuries. It is often eaten raw, as a curry, or in concentrated forms like pickles and chutney.
3. As a supplier of raw materials, Gencor intends on marketing *Caralluma fimbriata* extract in powdered form, with a recommended dose of 500mg twice per day. Although Gencor does not engage in the encapsulation or final manufacturing process, it is expected that the final product containing the new dietary ingredient will be available to consumers in various forms including capsule, softgel, tablet or liquid form form.
4. *Caralluma fimbriata* is listed in the Wealth of India, the Indian Health Ministry's comprehensive compilation on medicinal plants. It has been used as an appetite suppressant in India since the Vedic times and has also been used in folklore medicine to treat various conditions such as diabetes, pain, fever, and inflammation.
5. The therapeutic properties common to the *Caralluma* family have been widely reported in scientific literature. These include anti-inflammatory and anti-nociceptive properties, anti-hyperglycemic properties, and anti-ulcer and cytoprotective properties.
6. *Caralluma fimbriata* extract is obtained from dried and ground aerial parts of the plant. The extract used by Gencor will be manufactured by Green Chem, located at "Lakshmi" 5 BDA, Domlur 2nd State, 3rd Phase, Bangalore – 560 071, INDIA.
7. The key phytochemical constituents and potentially active molecules in *Caralluma fimbriata* include pregnane glycosides, flavone glycosides, megastigmane glycosides, bitter principles, saponins and various flavanoids.
8. The pregnane glycosides in *Caralluma fimbriata* are believed to prevent fat accumulation via blocking citrate lyase, similar to the mechanisms of *Garcinia cambogia*, already proven to be safe for weight loss. It is further believed that the pregnane glycosides also inhibit the sensory mechanisms of the hypothalamus.
9. No significant toxicity attributed to *Caralluma fimbriata* has ever been reported in the scientific literature. *Caralluma* cactus is non-toxic and is generally considered safe. In the attached acute oral toxicity study, no mortality was observed following the administration of a very high dose (5g/kg body weight) of *Caralluma Fimbriata* extract.
10. A recent double-blind, randomized human clinical trial conducted at the St. John's

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Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

August 25, 2004

Page 3

Medical College in Bangalore, India, reported a statistically significant reduction in weight with only mild to moderate gastrointestinal side-effects associated with the intake of *Caralluma fimbriata*. These side-effects usually subsided within one week. Post-trial monitoring of total cholesterol, LDL, HDL, triglycerides, serum creatinine, BUN, total protein, serum albumin, total bilirubin, conjugated bilirubin, AST and ALT, and alkaline phosphatase, gamma GT, and hemoglobin failed to reveal any overall toxicity from the extract. Attached to this notification are two samples of detailed patient reports related to the clinical trial. Upon request, Gencor would be happy to provide FDA with copies of similar reports for each active patient that participated in the trial.

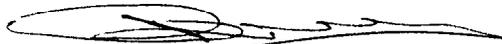
11. A second human clinical trial was conducted in Los Angeles, California, also reporting statistically significant weight loss and further confirming the safety of *Caralluma fimbriata*. That study reported minimal side effects (acidity; bloating) in only two patients, one of whom was on placebo.
12. The attached expert report of Dr. Harry G. Preuss, supported by testimonials from Dr. Ronald Lawrence and several experts in India, also confirms that there is no known toxicity associated with *Caralluma fimbriata*.

Based on the foregoing, we believe that FDA should accept this filing on behalf of Gencor Pacific, Inc. as providing sufficient evidence that *Caralluma fimbriata* extract, can reasonably be expected to be safe for human consumption.

If you require any additional information, please direct all correspondence to the undersigned.

Very truly yours,

ULLMAN, SHAPIRO & ULLMAN, LLP



Steven Shapiro
Vanessa Riviere

Encls.