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December 14, 2004

DEC 14 2004
AB/FDA

BY FEDERAL EXPRESS

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, Maryland 20740

Re: New Dietary Ingredient Notification for Kakadu Plum Concentrate

Dear Sir/Madam:

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, Access Business Group LLC (ABG), located at 7575 Fulton Street East, Ada, Michigan 49355, submits this new dietary ingredient (NDI) notification to the Food and Drug Administration (FDA) for its Kakadu Plum Concentrate product. Three hard copies and an electronic copy of the notification are enclosed.

ABG's Kakadu Plum Concentrate is an extract of the Kakadu Plum that has been concentrated and spray-dried to a powder form. The Australian Therapeutic Goods Administration (TGA) approved ABG's Kakadu Plum product for food and dietary supplement use in December of 2003. Kakadu Plums have a history of human consumption as a traditional food of the Aboriginal populations in the north and northwestern areas of Australia. The most popular current use for the Kakadu Plum is in gourmet jams and sauces served in restaurants, airlines and hotels, or sold as specialty foods.

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Office of Nutritional Products, Labeling and Dietary Supplements

December 14, 2004

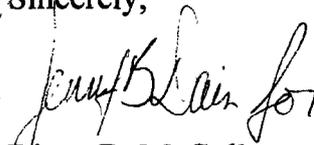
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ABG intends to market Kakadu Plum Concentrate as a new dietary ingredient for use in dietary supplements. Specifically, ABG intends to market Kakadu Plum Concentrate, containing 150 to 450 mg. Vitamin C per gram, to dietary supplement manufacturers for use as a natural source of Vitamin C in supplement products at levels consistent with current Vitamin C supplementation practice. ABG anticipates that its Kakadu Plum Concentrate will be used as a source of Vitamin C in supplement products such as multi-vitamin and multi-mineral supplements, Vitamin C supplements, antioxidant supplements, Vitamin C with flavonoids supplements and iron supplements. Such products would 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.

The NDI notification includes a discussion of the basis upon which ABG has concluded that its Kakadu Plum Concentrate, when used under the ordinary conditions of intended use as a source of Vitamin C in dietary supplements, does not present an unreasonable or significant risk to safety and is reasonably expected to be safe. Also provided are chemistry, manufacturing, and stability information; a description of the intended use; and a copy of the confidential TGA report on ABG's Kakadu Plum Concentrate.

If you have any questions concerning the enclosed NDI submission, please contact me as soon as possible by phone (202-737-4291) or by e-mail (dbm@hpm.com).

Sincerely,



Diane B. McColl

Counsel to Access Business Group LLC

DBM/dmh

Enclosure