

Memorandum

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Date: JUL 13 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Purple Corn Extract

Firm: Rainforest Botanicals, LLC

Date Received by FDA: April 14, 2005

90-Day Date: July 13, 2005

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

 Victoria Lutwak

19955-0316

RPT281



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

JUN 28 2005

Jose Ferreira
Rainforest Botanicals LLC
P.O. Box 770065
Miami, Florida 33177

Dear Mr. Ferreira:

This is to inform you that the notification you submitted, dated February 28, 2005, 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 April 14, 2005. Additional information that you sent, dated June 10, 2005, was received by the Agency on June 14, 2005. Your notification concerns the substance called "Purple Corn Extract" that you intend to market as a new dietary ingredient.

According to the notification you state that " 'purple corn extract' is intended for the use as a dietary supplement or an ingredient thereof for the purpose of providing a dietary antioxidant. As a precaution, it is not intended for use by pregnant or lactating women." In addition, the suggested dosage of "the dietary supplement containing purple corn (*Zea mays* L.) extract at a level of 250 mg. per capsule or tablet will be suggested to be taken two times per day."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains 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 deemed 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 "Purple Corn Extract" will reasonably be expected to be safe.

According to your notification, the new dietary ingredient that you call "Purple Corn Extract" is an alcohol extract of Peruvian corn cobs (*Zea mays* L.). It would be helpful to fully understand the identity of your new dietary ingredient, "Purple Corn Extract", if information about the specific extraction solvent was provided. Your notification does not clearly describe the dietary supplement product containing the new dietary ingredient, "Purple Corn Extract."

Several published articles were included in your notification each describing studies with materials identified as "purple corn color." The information submitted in your notification does not appear to be relevant to an evaluation of the safety of "Purple Corn Extract" that is the subject of your notification. The relationships between the materials tested in these studies and the material that is the subject of the notification is not clear. Your notification fails to explain the relationship between your product and the substances used in the references submitted. It is not clear to us how the test substances used in the referenced studies are qualitatively or quantitatively similar to your "Purple Corn Extract" product or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Purple Corn 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 April 14, 2005. 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 Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

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