DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

0419 '03 JAN 27 P2:13

Date: JAN 23 2003

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	*Momordica charantia L*
Firm:	Trinity International, LLC
Date Received by FDA:	July 01, 2002
90-Day Date:	September 29, 2002

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.

Angela F. Pope
Consumer Safety Officer

Attachments

95S-0316

RPT 137

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

SEP 12 2002

Therese P. Cerny
Trinity International, LLC
Distributor
6618 Saloma Avenue
Van Nuys, California 91405

Dear Ms. Cerny:

This letter is to inform you that the notification, dated June 25, 2002, pursuant to 21 U.S.C. 350b(a)(2) was received and filed by this office of the Food and Drug Administration (FDA) on July 1, 2002. Your notification concerns the substance stated as *"Momordica charantia L"* that you assert is a new dietary ingredient for use in "maintaining normal blood sugar levels."

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into commerce. This information must include 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 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the 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 new dietary ingredient 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 and injury. It is the responsibility of the manufacturer or distributor of a dietary supplement to ensure that the dietary supplement is safe, properly labeled and complies with all applicable requirements of the Federal Food, Drug and Cosmetic Act and implementing regulations in Title 21 of the Code of Federal Regulations as well as any other applicable Federal laws and regulations.

There is inadequate information in your notification to determine whether there is an adequate basis to conclude that the use of a dietary supplement that contains *"Momordica charantia L"* 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 it does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Further, the notification you sent us concerning *"Momordica charantia L"* is incomplete and does not provide the minimum information required under 21 CFR 190.6 (copy enclosed) for a new dietary ingredient notification. You also may wish to review FDA's Web site at http://www.cfsan.fda.gov/~dms/ds-ingrd.html for additional details on new dietary ingredient notification requirements. Your notification does not fully comply with 21 CFR 190.6. For example, it fails to:

- Include copies or reprints of references cited in support of your conclusion that the new dietary ingredient is reasonably expected to be safe when used as recommended in a dietary supplement. The information you submitted from an article published in the Medical Observer, September 2001 represents a summary report that is not accompanied by copies of the actual studies cited to verify whether they were designed and conducted in a way to achieve scientifically reliable results. Other information provided in your notification appears to be documentation that provides evidence that your product is registered as a food supplement rather than a determination of the safety of your product.

- Provide full descriptions of the studies, not abstracts or summaries. If they are written in a foreign language, they must be accompanied by accurate and complete English translations.

If you desire, you may send us the required information to correct the deficiencies in your current notification by submitting a new notification, in triplicate, that is complete and fully complies with 21 CFR 190.6. The date we receive this additional information is considered the new filing date for your new notification.

Although not required, if you decide to submit a new notification, we would appreciate your sending us an additional two copies for a total of five copies (i.e., original and four copies) to facilitate our internal administrative processing of the notification. Please make sure that all copies you send us contain the same information in accordance with 21 CFR 190.6.

Your notification will be kept confidential for 90 days after the filing date. Therefore, after September 29, 2002, the notification, its addenda and related correspondence from FDA will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

Prior to September 29, 2002, you may wish to identify in writing specifically what information you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

We noticed that your notification does not include facsimile (fax) number or an electronic mail address as other ways to contact you. Although you are not required to provide us with this information, we would appreciate your sharing it with us, if it exists, as quicker ways to communicate with you. If you have additional questions, please contact us at (301) 436-2371.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

81011

June 25, 2002

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Science and Applied Nutrition
5100 Paintbranch Parkway
College Park, MD 20740-3835

Re: New Dietary Ingredient Notification: *Momordica charantia* L.

Dear Sir/Madam:

Enclosed please find 1 original and 4 copies of the "Pre-Market Notification of a New Dietary Ingredient: *Momordica charantia* L."

If you have any questions regarding this notification, please do not hesitate to call me at the number below. Thank you for your attention to this matter.

Sincerely,

Therese P. Cerny
Trinity International, LLC
Tel: (818) 786-0480
E-mail: theresecerny@yahoo.com

Enclosures

Herbal Dietary Supplement 100 Capsules

AMARGOZIN

BITTER MELON (AMPALAYA)
Capsule 500 mg

INGREDIENTS: Each capsule contains 500 mg powdered Ampalaya leaves *(Charantia momordica, L.)*.

SUGGESTED USE: Take 1-3 capsules three times a day

PRECAUTION: Possibility of adverse effects on pregnant women has not been studied.

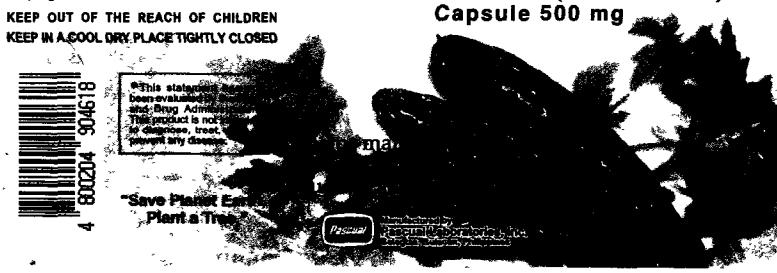
KEEP OUT OF THE REACH OF CHILDREN

KEEP IN A COOL DRY PLACE TIGHTLY CLOSED

4 800204 904618

*This statement has been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

"Save Planet Earth Plant a Tree"



Supplement Facts

Serving Size 1 Capsule (500 mg)

Amount per Serving			% DailyValue*
Ampalaya powder Charantia momordica (L.) (leaf 500 mg) **	-		-
Calories	2		-
Fat	0		0%
Crude Fiber	41.6	mg	< 1 %
Carbohydrates	<1	gm	< 1 %
Protein	156.7	mg	< 1%
Cholesterol	0		0%
Calcium	24.7	mg	< 1%

* Percent Daily Values are based on a 2,000 calorie diet.
** Daily Value (DV) not established.

PLB483S

OTENCY GUARANTEED THROUGH

onth and Year:

Lot No.:

"Pre-Market Notification of a New Dietary Ingredient: *Momordica charantia* L."

Manufacturer:

Pascual Laboratories, Inc.	Km. 31 McArthur Highway
Quezon City, Metro Manila	Balagtas, Bulacan
Philippines	Philippines
(Corporate Headquarters)	(Manufacturing Plant)

Distributor:

Trinity International, LLC
6618 Saloma Ave.
Van Nuys, CA 91405
U.S.A.

New Dietary Ingredient:

Latin Binomial Name:	*Momordica charantia* L.
Author:	Linnaeus, Carolus
Common names:	Bitter Melon, Ampalaya, Amorgoso, Balsam Apple, Balsam Pear, African Cucumber, Karela

New Dietary Supplement:

Brand Name:	Amargozin (100 capsules/500 mg)
Description of Dietary Supplement:	Green to brownish green powder form of the fruit and leaves, no seeds, not an extract. No other ingredients. Capsule size is #0, transparent.
Amount of New Dietary Ingredient:	500 mg powdered *Momordica charantia* L. leaves and fruit, no seeds. Two Amargozin capsules is equivalent to one serving of the fruit.
Recommended Use:	Maintains normal blood sugar levels by promoting normal glucose metabolism. 1-3 capsules 3x/day 45 min. before meals with 10-12 oz. water. Blood sugar levels must be monitored closely to titrate proper dosage.
Sub-Groups Intended For:	People with normal to high blood sugar levels.
Sub-Groups Not Intended For:	Not applicable.

Evidence of Safety:

History of Use: *Momordica charantia* L. is commonly eaten as a vegetable in tropical areas such as East Africa, Asia, the Caribbean and South America. Fruit and leaves are used in culinary preparations and fruit is also used traditionally in controlling blood sugar levels. It is cultivated in many parts of the world for consumption as a vegetable. As the name implies, Bitter Melon fruit and juice are extremely bitter. Cooking with appropriate spices reduces the bitterness somewhat. While fresh fruit is available at Asian grocery stores, only a few concentrated products are available as supplements.

Clinical Studies*: Clinical studies were performed by the National Integrated Research Program on Medicinal Plants (NIRPOMP) under the Philippine Council for Health Research and Development (PCHRD) part of the Department of Science and Technology (DOST).
All studies were conducted in accordance with the World Health Organization (WHO) prescribed standards for establishing the safety and efficacy of medicinal plants.
**See attachments: "Bitter Pill For A Sweet Disease" (Medical Observer, Sept.2001), World Health Organization Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.*

Safety Profile**:
1. Registered as a Food Supplement with the Bureau of Food and Drugs (BFAD) Philippines.
2. Certified by the Department of Health (DOH)/Philippine Institute of Traditional and Alternative Healthcare (PITAHC).
3. Validated by the Food and Nutrition Research Institute (FNRI) for its nutritional content.

***See attachments: BFAD Certificate of Product Registration, DOH/PITAHC Certificate, FNRI Food Composition Tables*