

Memorandum

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Date:

 JUL 21 2006

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: Pomx: pomegranate fruit polyphenol extract

Firm: Pom Wonderful, LLC

Date Received by FDA: April 24, 2006

90-Day Date: July 23, 2006

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

RPT349



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

JUL 7 2006

Mark L. Dreher, Ph.D.
Vice President
Scientific and Regulatory Affairs
Pom Wonderful, LLC
11444 West Olympic Boulevard, Suite 310
Los Angeles, California 90064

Dear Dr. Dreher:

This is to inform you that the notification, dated April 19, 2006, you submitted pursuant to 21 U.S.C. 3501b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) was received by the Food and Drug Administration (FDA) on April 24, 2006 and additional information was received on May 1, 2006. Your notification concerns the new dietary ingredient pomegranate (*Punica granatum* L. cv. 'Wonderful') fruit polyphenol extract that you intend to market as a dietary ingredient in your product called "Pom_x".

According to your notice the recommended conditions of use for "Pom_x" containing pomegranate fruit polyphenol extract are to take two 350 mg capsules or tablets per day, or one 500 mg capsule or tablet per day, or one 700 mg capsule or tablet per day.

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 significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing pomegranate fruit polyphenol extract will reasonably be expected to be safe.

Based on the information submitted in your notification, FDA was unable to determine the identity of your proposed new dietary ingredient, other than the statement that it consists of polyphenols. While your notification states that your proposed ingredient contains polyphenols, your notification failed to provide any information about the specific components of your proposed new dietary ingredient. For example, your notification did not provide the technical specifications, manufacturing process, or any methods of analysis for your new dietary ingredient. This information would have helped FDA to identify your proposed new dietary ingredient.

In addition, your notification provided information about the safe consumption of pomegranates and pomegranate juice as food, however, your notification failed to provide history of use data and information for your proposed new dietary ingredient.

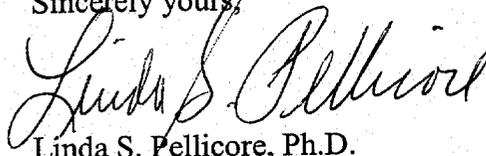
Further, your notification failed to provide data and information to support the safe human consumption of your proposed new dietary ingredient.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Pom_x," 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 24, 2006. 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 Victoria Lutwak at (301) 436-1775.

Sincerely yours,



Linda S. Pellicore, Ph.D.

Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements,
Center for Food Safety and Applied Nutrition



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May 1, 2006

Linda Pellicore
Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Linda:

This letter is in response to your request for additional information about Pomx.

Name of the dietary ingredient

Pomx is a pomegranate (*Punica granatum* L., Wonderful variety) fruit polyphenol extract.

Description of dietary supplements that contain the dietary ingredient

This amends the descriptions originally submitted on April 19, 2006.

The following forms and dosages of the dietary ingredient will be marketed as a dietary supplement to increase the total dietary intake of plant polyphenols:

1. A tablet containing 500 mg pomegranate polyphenols in the form of Pomx.
Recommended use: Take 1 tablet once per day.
2. A capsule containing 500 mg pomegranate polyphenols in the form of Pomx.
Recommended use: Take 1 capsule once per day.
3. A tablet containing 350 mg pomegranate polyphenols in the form of Pomx.
Recommended use: Take 2 tablets per day.
4. A capsule containing 350 mg pomegranate polyphenols in the form of Pomx.
Recommended use: Take 2 capsules per day.
5. A tablet containing 700 mg pomegranate polyphenols in the form of Pomx.
Recommended use: Take 1 tablet once per day.
6. A capsule containing 700 mg pomegranate polyphenols in the form of Pomx.
Recommended use: Take 1 capsule once per day.

310.966.5800
310.966.5801 Fax
11444 West Olympic Blvd
Los Angeles, CA 90064



A 500mg daily dose of Pomx delivers pomegranate polyphenols in an amount equivalent to about 6-8 fl oz of pomegranate juice.

A 700mg daily dose of Pomx delivers pomegranate polyphenols in an amount equivalent to about 8-9 fl oz of pomegranate juice.

The USDA Food Guide recommends 4 fruit servings per day, which is the equivalent of 16 fl oz of fruit juice per day.

Product excipients

Tablets:

- Silicon Dioxide/Aerosil 200
- Magnesium Stearate, vegetable grade

Capsules:

- NPcaps, plant-based capsules formulated with Pullulan (a water-soluble polysaccharine), supplied by Capsugel

Extraction process description

POMx powder is produced in a two step process: (1) extraction of polyphenols from pomegranate fruit, and (2) purification of the extract to produce a highly concentrated polyphenol powder. Extraction is performed during the fruit harvest using pressed pomegranate skins and arils. Each of these process steps is briefly described further below.



The polyphenol solution is food-grade spray-dried to produce a pomegranate extract powder containing _____ polyphenols (quantified as Gallic Acid Equivalence). The powder is used as an ingredient in supplements and functional foods.

Respectfully submitted,

Mark L. Dreher

Mark L. Dreher, PhD
Vice President, Scientific
and Regulatory Affairs
Pom Wonderful, LLC
11444 West Olympic Blvd, Suite 310
Los Angeles, CA 90064
mdreher@pomwonderful.com



April 19, 2006

Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835.

APR 24 2006

AIMS 2006-3650

To Whom it May Concern:

Pursuant to 21 CFR 190.6, notification is hereby provided of a new dietary ingredient.

Name and address of the manufacturer of the new dietary ingredient:

Pom Wonderful, LLC
11444 West Olympic Blvd, Suite 310
Los Angeles, CA 90064

Name of the new dietary ingredient:

Pom_X - Pomegranate (*Punica granatum*, Wonderful variety) fruit polyphenol extract.

Description of dietary supplements that contain the new dietary ingredient:

Level of the new dietary ingredient in the dietary supplement

1. A tablet containing 500 mg pomegranate polyphenols in the form of Pom_X
2. A capsule containing 500 mg pomegranate polyphenols in the form of Pom_X
3. An admixture containing 500 mg pomegranate polyphenols in the form of Pom_X
4. A liquid suspension containing 500 mg pomegranate polyphenols in the form of Pom_X

Recommended conditions of use:

Recommended as a dietary supplement to increase the total dietary intake of plant polyphenols at the following dosages:

1. Take 1 tablet once per day
2. Take 1 capsule once per day
3. Take 1 dose admixture once per day
4. Take 1 dose liquid suspension once per day

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History of use and evidence of safety:

Pomegranates have a long history of consumption as fresh fruit. In recent years, pomegranates grown exclusively in California are consumed as commercially produced pomegranate juice, a rich dietary source of polyphenols.

Pom Wonderful pomegranate juice, tested with the Folin-Ciocalteu reagent, contains 2,566 mg of total polyphenols per liter (Gil et al, 2000, Table 4). An 8 fl oz serving (240 mL) of the juice contains 616 mg of polyphenols.

A single daily dose of the new dietary ingredient Pom_X delivers 500mg of pomegranate polyphenols, an amount equivalent to about 6.5 fl oz of pomegranate juice.

Respectfully submitted,

A handwritten signature in black ink that reads 'Mark L. Dreher'.

Mark L. Dreher, PhD
Vice President, Scientific
and Regulatory Affairs
Pom Wonderful, LLC
11444 West Olympic Blvd, Suite 310
Los Angeles, CA 90064
mdreher@pomwonderful.com

Enclosure:

Gil, M. I., Tomas-Barberan, F. A., Hess-Pierce, B., Holcroft, D. M., & Kader, A. A. (2000). Antioxidant activity of pomegranate juice and its relationship with phenolic composition and processing. *J Agric Food Chem*, 48(10), 4581-4589.