DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: FEB 10 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: Psyllium hemicellulose

Firm: The Procter and Gamble Company

Date Received by FDA: November 14, 2005

90-Day Date: February 12, 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

JAN 27 2006

Nadia N. St. Luce, Ph.D.
US Regulatory Affairs, Personal Health Care
The Proctor and Gamble Company
Health Care Research Center
8700 Mason-Montgomery Road
Mason, Ohio 45040-9462

Dear Dr. St. Luce:

This is to inform you that the notification you submitted, dated November 11 , 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 November 14, 2005. Your notification concerns the substance called "psyllium hemicellulose," *Plantago ovata* Forssk., that you intend to market as a new dietary ingredient.

According to your notice the conditions for use for "psyllium hemicellulose" are the following: "The recommended daily intake will be 2.5 grams of "psyllium hemicellulose" powder in 8 ounces of water to be taken up to three times per day. This will result in a maximum intake of "psyllium hemicellulose" of 7.5g/day. The product will be labeled that it is not intended or recommended for use by children under 6 unless provided under physician's guidance." Directions: "One heaping TEASPOON in 8 ounces of water up to three times daily. Under 6 years: Consult a doctor. NOTICE: Mix this product with at least 8 oz (a full glass) of water. Taking without sufficient liquid may cause choking. Do not take if you have difficulty swallowing."

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 21U.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 "psyllium hemicellulose" will reasonably be expected to be safe.

It is unclear how the test substances discussed in some of the referenced studies are qualitatively or quantitatively similar to your new dietary ingredient or how these studies are relevant to evaluating the safe use of your new dietary ingredient "psyllium hemicellulose" 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 "psyllium hemicellulose," 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 November 14,, 2005. 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 further questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

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

New Dietary Ingredient:

Psyllium Hemicellulose

November 11, 2005

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