

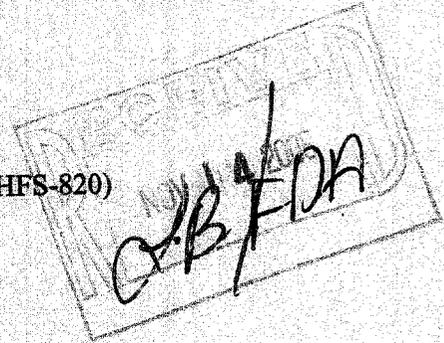
**Cover Page**



The Procter & Gamble Company  
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November 11, 2005

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)  
Center for Food Safety and Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



**Re: New Dietary Ingredient (NDI) Notification for Psyllium Hemicellulose**

Dear Sir/Madam:

In accordance with 21 CFR § 190.6, The Procter & Gamble Company (P&G), is hereby notifying the Food and Drug Administration (FDA) of its intent to market the dietary ingredient psyllium hemicellulose. Psyllium hemicellulose is the predominant soluble fiber component of psyllium husk, which is currently marketed under the Brand name Metamucil.

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 a physician's guidance.

In this submission, we were aware of FDA's recent call for comments on the premarket notification program for new dietary ingredients (69 FR 202, PP.61680-61685; October 20, 2004). Based on this FDA input, we have included information in this submission on the identification, analysis and manufacture of the subject dietary ingredient. We have also addressed key questions posed by FDA in the FR notice to help clearly establish a reasonable expectation of safety. Based on the information in the following NDI submission, we believe that FDA should accept this filing on behalf of P & G as providing sufficient evidence that psyllium hemicellulose, when used under the conditions recommended, can reasonably be expected to be safe for human consumption.

Psyllium hemicellulose is listed as an approved active ingredient in the Laxative Drug Products for Over-the-Counter Human Use Tentative Final Monograph (FR 50, #10, Jan. 15, 1985; FR 51, #190, Oct. 1, 1986) at an oral dosage up to 30 grams daily in divided doses of 2.5 to 7.5 grams per dose for adults and children 12 years of age and over. For children 6 to under 12, the dose is up to 15 grams daily in divided doses of 2.5 to 3.75 grams per dose. Subsequently, the agency recommended that active ingredients in OTC drugs that do not have USP (United States Pharmacopoeia) monographs may not be approved in final monographs. Consequently, P & G submitted a USP monograph for psyllium hemicellulose which was reviewed and published in final form in January, 2005 to ensure inclusion in the final Laxative Monograph.

2005-768  
Aims



Based on the fact that psyllium hemicellulose is an FDA approved active ingredient for OTC laxative drugs at doses of up to 30 grams daily for adults, P&G is aware that the agency considers this ingredient safe for oral ingestion. Additionally, psyllium hemicellulose has been consumed as the main soluble fiber component (75%) of psyllium husk as a daily dietary fiber supplement for many years. However, since psyllium hemicellulose has not been separately marketed as a stand-alone soluble fiber dietary supplement in the US before 1994, P&G is submitting this NDI to support future dietary supplement use of this ingredient.

We believe that this document provides reasonable evidence that it is safe to use psyllium hemicellulose as a dietary (fiber) supplement ingredient. The product will not be marketed until after a period of at least 75 days from acceptance of this notification by the Agency. Should you have any questions regarding this notification, please contact Dr. Nadia St. Luce at 513-622-5566 or e-mail her at [stluce.nn@pg.com](mailto:stluce.nn@pg.com). We will respond promptly to any questions you might have.

Sincerely,

THE PROCTER & GAMBLE COMPANY

Nadia N. St. Luce, Ph.D.  
US Regulatory Affairs, Personal Health Care