

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****18 CFR Part 284****[Docket No. RM03-10-000]****Amendments to Blanket Sales Certificates; Extension of Comment Period**

July 25, 2003.

**AGENCY:** Federal Energy Regulatory Commission, DOE.**ACTION:** Notice of proposed rulemaking; extension of comment period.

**SUMMARY:** On June 26, 2003, the Federal Energy Regulatory Commission issued a Notice of Proposed Rulemaking (NOPR) (68 FR 40207, July 7, 2003) seeking comments on amending the blanket certificates for unbundled gas sales services held by interstate natural gas pipelines and the blanket marketing certificates held by persons making sales for resale of gas at negotiated rates in interstate commerce. The date for filing comments is being extended at the request of various interested parties.

**DATES:** Comments on issues posed by the NOPR shall be filed on or before August 18, 2003. Reply comments shall be filed on or before September 18, 2003.

**ADDRESSES:** Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

**FOR FURTHER INFORMATION CONTACT:** Magalie R. Salas, Secretary 888 First Street, NE., Washington, DC 20426, (202) 502-8400.

On July 23 and 24, 2003 Duke Energy Corporation (Duke) and Public Service Electric and Gas Company (PSE&G) filed respective motions for a 60-day extension of time for the filing of initial comments in response to the Commission's Notice of Proposed Rulemaking (NOPR) regarding blanket sales certificates, issued June 26, 2003, in the above-docketed proceeding. In their motions, Duke and PSE&G state that permitting a 60-day extension to comment will allow interested parties to adequately review, analyze and formulate appropriate and constructive comments for the Commission to consider in its final rule on amendments to blanket sales certificates.

Upon consideration, notice is hereby given that the time for filing initial comments in response to the Commission's June 25, 2003 NOPR is extended from August 6, 2003, to and including August 18, 2003. Reply

comments shall be filed on or before September 18, 2003.

Magalie R. Salas,  
Secretary.

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**BILLING CODE 6717-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 310 and 334****[Docket No. 1978N-036L]****RIN 0910-AA01****Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the administrative record and proposing to amend the tentative final monograph (proposed rule) for over-the-counter (OTC) laxative drug products to reclassify the bulk-forming laxative psyllium ingredients (psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond)), psyllium seed husks, plantago ovata husks, and plantago seed)) in a granular dosage form from Category I (generally recognized as safe and effective and not misbranded) to Category II (not generally recognized as safe and effective or misbranded). The granular dosage form affected by this proposal includes, but is not limited to, any granules that are swallowed dry prior to drinking liquid; any granules that are dispersed, suspended, or partially dissolved in liquid prior to swallowing; any granules that are chewed, partially chewed, or unchewed, and then washed down (or swallowed) with liquid; and any granules that are sprinkled over food. FDA is issuing this proposed rulemaking after considering data and information on the safety of some currently marketed products containing psyllium in a granular dosage form. This proposed rulemaking does not apply to nongranular dosage forms of psyllium, such as powders. FDA has determined that psyllium in a granular dosage form presents an unacceptable safety risk to consumers because esophageal obstruction continues to occur despite currently required label warnings and directions.

This proposal is part of FDA's ongoing review of OTC drug products.

**DATES:** Submit written or electronic comments by November 3, 2003; submit written or electronic comments on the FDA's economic impact determination by November 3, 2003. See section IX for the effective date of any final rule that may publish based on this proposal.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Arlene Solbeck, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the advance notice of proposed rulemaking (ANPRM) for OTC laxative, antidiarrheal, emetic, and antiemetic drug products (40 FR 12902 at 12906, March 21, 1975), the advisory review panel on OTC laxative, antidiarrheal, emetic, and antiemetic drug products (the Panel) recommended Category I status for the OTC bulk laxative psyllium ingredients, which include plantago seed, plantago ovata husks, psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), and psyllium seed husks. FDA concurred with the Panel's Category I classification of these ingredients in the tentative final monograph (TFM) published in the **Federal Register** of January 15, 1985 (50 FR 2124 at 2152).

In the ANPRM, the Panel recommended a warning statement (§ 334.52(a)(1) 21 CFR 334.52(a)(1)) for bulk forming laxatives that advised drinking a full glass, 8 ounces (oz), of liquid with each dose and direction statements (§ 334.10(f)) advising adequate fluid intake. The Panel concluded that adequate fluid intake was necessary for the proper use of bulk-forming laxatives because esophageal and intestinal obstruction had occurred from ingesting bulk-forming laxatives with insufficient water or in the presence of certain disease conditions (40 FR 12902 at 12908). FDA discussed the risk of esophageal obstruction from certain bulk laxative ingredients, including water-soluble gums, and the need for adequate fluid intake (8 oz) with each dose in comments 36 and 37 of the TFM (50 FR 2124 at 2131 and 2132). FDA