FR 18105), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0571. The approval expires on May 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9824 Filed 6–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0369]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 10, 2006 (71 FR 7048), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0583. The approval expires on April 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9826 Filed 6–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0457]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Substances Generally Recognized as Safe: Notification Procedure'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 7, 2006 (67 FR 17892), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0342. The approval expires on May 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9827 Filed 6–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0237]

Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which an applicant may obtain an assignment or designation determination.

DATES: Submit written or electronic comments on the collection of information by August 21, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—21 CFR Part 3 (OMB Control Number 0910–0523)—Extension

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Public Law 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any of the following combinations: (1) A drug and a device; (2) a device and a biological; (3) a biological and a drug; or (4) a drug, a device, and a biological. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biologicals, and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 3	43	1	43	24	1,032

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9900 Filed 6–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006O–0232]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Laxative Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following condition as part of FDA's ongoing review of over-the-counter (OTC) drug products: Sodium picosulfate, up to 10 milligrams (mg), as a laxative single active ingredient. FDA reviewed a time and extent application (TEA) for this condition and determined that it is eligible for consideration in our OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether this condition can be generally recognized as safe and effective (GRAS/E) for its proposed OTC use.

DATES: Submit data, information, and comments by September 20, 2006.

ADDRESSES: Submit comments, data, and information to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO Bldg. 22, Mail Stop 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14 (a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.