respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Health Care Professionals on the Food Safety and Nutrition Information that they Provide to Pregnant Women

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct a survey of health care professionals to determine what information, advice, and recommendations they are offering to pregnant women about the following topics: (1) Methyl mercury and seafood consumption; (2) Listeriosis prevention; (3) weight control and nutrition; (4) dietary supplement usage; (5) food allergies; (6) Toxoplasmosis prevention; and (7) infant feeding practices. FDA is interested in obtaining this data since FDA has recently issued advice for pregnant women about food safety risks and diet risks such as mercury in seafood, Listeriosis, and Toxoplamosis. (''Food Safety for Moms-to-Be'', 2005 and ''What You Need to Know about Mercury in Fish and Shellfish'', 2004). Data from this survey will be used to evaluate whether health care professionals are aware of this advice and if they are educating their patients about information in the FDA advisories.

FDA will also use this survey to get a better understanding of what resources health care professionals use to stay abreast of current practices for caring for pregnant women. This will help FDA provide timely recommendations to health care professionals that will reach the largest audience.

A sample of 400 obstetrician/gynecologists, 200 nurse practitioners, 200 nurse midwives, 200 physician assistants, and 200 dietitians from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) will be included in this survey. The sample of nurse practitioners, nurse midwives, and physician assistants will be drawn from those specializing in obstetrics. The samples will be randomly selected from lists obtained from national associations. The survey will be conducted using a mailed questionnaire. Cognitive interviews and a pretest will be conducted prior to fielding the survey.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,200 - Survey	1	1,200	.167	200.4
75 - Pretest	1	75	.167	12.5
16 - Cognitive Interview	1	16	.75	12
Total	1	1,291		224.9

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

The burden estimate is based on FDA's experience with previous surveys.

Dated: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8566 Filed 6–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0426]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Notice of Participation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Notice of Participation'' 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 March 16, 2006 (71 FR 13602), 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 0910–0191. 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: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8567 Filed 6–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0393]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Investigational New Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Investigational New Drug Regulations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management

Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 17, 2006 (71 FR 8590), 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 0910–0014. 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: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8568 Filed 6–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0081]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing Act of 1987

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by July 3, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing Act of 1987: Administrative Procedures, Policies, and Requirements—21 CFR Part 203—(OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the PRA (44 U.S.C. 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100–293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements:

TABLE 1.—REPORTING REQUIREMENTS

21 CFR Section	Reporting Requirements
21 CFR 203.11	Applications for reimportation to provide emergency medical care.
21 CFR 203.30(a)(1) and (b)	Drug sample requests (drug samples distributed by mail or common carrier).
21 CFR 203.30(a)(3), (a)(4), and (c)	Drug sample receipts (receipts for drug samples distributed by mail or common carrier).
21 CFR 203.31(a)(1) and (b)	Drug sample requests (drug samples distributed by means other than the mail or a common carrier).
21 CFR 203.31(a)(3), (a)(4), and (c)	Drug sample receipts (drug samples distributed by means other than the mail or a common carrier).
21 CFR 203.37(a)	Investigation of falsification of drug sample records.
21 CFR 203.37(b)	Investigation of a significant loss or known theft of drug samples.
21 CFR 203.37(c)	Notification that a representative has been convicted of certain offenses involving drug samples.
21 CFR 203.37(d)	Notification of the individual responsible for responding to a request for information about drug samples.
21 CFR 203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.

TABLE 2.—RECORDKEEPING REQUIREMENTS

21 CFR Section	Recordkeeping Requirements
21 CFR 203.23(a) and (b)	Credit memo for returned drugs.
21 CFR 203.23(c)	Documentation of proper storage, handling, and shipping conditions for returned drugs.