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.

TABLE 2.—RECORDKEEPING REQUIREMENTS—Continued

21 CFR Section	Recordkeeping Requirements
21 CFR 203.30(a)(2) and 21 CFR 203.31(a)(2)	Verification that a practitioner requesting a drug sample is licensed or authorized to prescribe the product.
21 CFR 203.31(d)(1) and (d)(2)	Contents of the inventory record and reconciliation report required for drug samples distributed by representatives.
21 CFR 203.31(d)(4)	Investigation of apparent discrepancies and significant losses revealed through the reconciliation report.
21 CFR 203.31(e)	Lists of manufacturers' and distributors' representatives.
21 CFR 203.34	Written policies and procedures describing administrative systems.
21 CFR 203.37(a)	Report of investigation of falsification of drug sample records.
21 CFR 203.37(b)	Report of investigation of significant loss or known theft of drug samples.

TABLE 2.—RECORDKEEPING REQUIREMENTS—Continued

21 CFR Section	Recordkeeping Requirements
21 CFR 203.38(b)	Records of drug sample distribution identifying lot or control numbers of samples distributed. (The information collection in 21 CFR 203.38(b) is already approved under OMB Control Number 0910–0139).
21 CFR 203.39(d)	Records of drug samples destroyed or returned by a charitable institution.
21 CFR 203.39(e)	Record of drug samples donated to a charitable institution.
21 CFR 203.39(f)	Records of donation and distribution or other disposition of donated drug samples.
21 CFR 203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
21 CFR 203.50(a)	Drug origin statement.
21 CFR 203.50(b)	Retention of drug origin statement for 3 years.
21 CFR 203.50(d)	List of authorized distributors of record.

The reporting and recordkeeping requirements are intended to help achieve the following goals:

1. To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care;

2. To ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample;

3. To limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other health care entities at the request of a licensed or authorized practitioner;

4. To require licensed or authorized practitioners to request prescription drug samples in writing;

5. To mandate storage, handling, and recordkeeping requirements for prescription drug samples;

6. To prohibit, with certain exceptions, the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or other health care entities, or which were donated or supplied at a reduced price to a charitable organization; and

7. To require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.11	12	1	12	.5	6
203.30(a)(1) and (b)	61,961	12	743,532	.06	44,612
203.30(a)(3), (a)(4), and (c)	61,961	12	743,532	.06	44,612
203.31(a)(1) and (b)	232,355	135	31,367,925	.04	1,254,717
203.31(a)(3), (a)(4), and (c)	232,355	135	31,367,925	.03	941,038
203.37(a)	25	1	25	6.00	150
203.37(b)	200	1	200	6.00	1,200
203.37(c)	50	1	50	1.00	50
203.37(d)	2,208	1	2,208	.08	177
203.39(g)	3,221	1	3,221	2.00	6,442
Total Reporting Burden Hours					2,293,004

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

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768
203.39(g)	3,221	1	3,221	8.00	25,768
203.50(a)	0	0	0	0	0
203.50(b)	0	0	0	0	0
203.50(d)	0	0	0	0	0
Total Recordkeeping Burden Hours					409,409

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

In the **Federal Register** of March 16, 2006 (71 FR 13599), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: May 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8569 Filed 6–1–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0215]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Valid or Will Not Be Infringed

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 reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement.

DATES: Submit written or electronic comments on the collection of information by August 1, 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: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal