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 0910–0581. The approval expires on June 30, 2012. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: July 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17330 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0606]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Export of Food and Drug Administration Regulated Products: Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Export of Food and Drug Administration Regulated Products: Export Certificates'' 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 Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 3, 2009 (74 FR 9247), 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 0910–0498. The approval expires on October 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: July 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17331 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0454]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Contact Substances Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Contact Substances Notification System'' 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 Information Management (HFA–710),Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 4, 2008 (73 FR 73936), 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 0910–0495. The approval expires on May 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: July 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17332 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0131]

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 August 21, 2009.

ADDRESSES: 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, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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; 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:

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
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
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 by the appropriate State authority 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
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.

In the **Federal Register** of March 24, 2009 (74 FR 12365) (March 24, 2009, document), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one comment.

Comment Summary: The comment pertained to the recordkeeping requirements in § 203.50(a) and (b) (21 CFR 203.50(a) and (b)).

The comment concluded that FDA's estimate of ''0'' recordkeeping hours for these regulations in table 2 of the March 24, 2009, document was in error. In summary, the comment contended: (1) Pedigrees must be passed by non-authorized distributors of record prior to each wholesale distribution; (2) all wholesale distributors that provide or receive pedigrees after December 1, 2006, must retain copies of the pedigrees for 3 years; and (3) those records must include names and addresses of all parties to the transaction and the date of the transactions.

The comment offered no estimates for the recordkeeping provisions in § 203.50(a) and (b). The comment explained that it is unable to suggest estimates for the burden hours because most of its members ''have likely received a designation of ''ADR'' status by most drug manufacturers for most of the prescription drug products that they purchase, and they provide pedigrees only on a limited basis.'' Thus, the comment said, there are a large number of distributors that are not members of its organization but are subject to the pedigree requirements and, therefore, the burden hours that its members alone accrue would not be reflective of the entire population of distributors that are affected, and would likely be a minority of the total burden hours that all distributors experience.

The comment recommended that FDA ''conduct a PRA review and estimate of the paperwork burden for healthcare distributors to comply with these regulations.''

FDA Response: FDA appreciates the comment and, as requested, we plan to conduct research to obtain estimates for the burden hours that may be currently incurred by distributors to comply with the recordkeeping provisions in § 203.50. In this regard, we are requesting that interested persons submit, to the docket identified in the heading of this document, data on the burden hours currently incurred by distributors to comply with the recordkeeping provisions in § 203.50. In addition, in response to the comment, we are revising table 2 of the March 24, 2009, document to add recordkeeping estimates for § 203.50. We used these estimates in previous **Federal Register** notices based on information we received at that time, and no comments were received on these burden hours. If our research results in new data that differs from these estimates, we will amend the approval for OMB control number 0910–0435 to include revised estimates for these provisions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
203.11	1	1	1	.5	30 minutes
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)	50	4	200	.25	50
203.37(b)	50	40	2,000	.25	500
203.37(c)	1	1	1	1	1
203.37(d)	50	1	50	.08	4
203.39(g)	1	1	1	1	1
Total					2,285,535.30

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	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	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2,000	6	12,000
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2.0	1,382
Total					332,769

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

Dated: July 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17394 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Study of Factors Influencing Consumer Choices Among Health Plans and Clinicians.'' In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection. This proposed information collection was previously published in the **Federal Register** on September 3rd, 2008 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. This notice differs from the 60 day notice in the following ways: (1) The number of responses has been decreased from 6,000 to 4,950, (2) the burden hours are decreased from 838 to 709, and (3) the descriptions of each experimental arm in the sections: Clinician Choice Experimental Design and Health Plan Choice Experimental Design were removed.

DATES: Comments on this notice must be received by August 21, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrq.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

''Study of Factors Influencing Consumer Choices Among Health Plans and Clinicians''

AHRQ proposes to use an experimental design to determine factors that influence consumers' understanding and use of performance information to select among health plans and clinicians. The experimental design will include two parallel experiments, one designed to assess factors influencing choice of health plans and one designed to assess factors influencing choice of individual doctors. For both the health plan and clinician choice experiments respondents will be randomly assigned to one of six experimental arms that vary according to the type and complexity of performance information