4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0279]

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

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.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: 202-395-7285, or emailed 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

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 No. 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). 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 existing reporting and recordkeeping requirements:

Table 1.--Reporting Requirements

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

Table 2.--Recordkeeping Requirements

21 CFR Section	Requirement
203.23(a) and (b)	Credit memo for returned drugs.
203.23(c)	Documentation of proper storage, handling, and shipping conditions for returned drugs.
203.30(a)(2) and 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.
203.31(d)(1) and (d)(2)	Contents of the inventory record and reconciliation report required for drug samples distributed by representatives.
203.31(d)(4)	Investigation of apparent discrepancies and significant losses revealed through the reconciliation report.
203.31(e)	Lists of manufacturers' and distributors' representatives.
203.34	Written policies and procedures describing administrative systems.
203.37(a)	Report of investigation of falsification of drug sample records.
203.37(b)	Report of investigation of significant loss or known theft of drug samples.
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).
203.39(d)	Records of drug samples destroyed or returned by a charitable institution.
203.39(e)	Record of drug samples donated to a charitable institution.
203.39(f)	Records of donation and distribution or other disposition of donated drug samples.
203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
203.50(a)	Drug origin statement.
203.50(b)	Retention of drug origin statement for 3 years.
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 November 14, 2014 (79 FR 68273), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
203.11 Re-importation	1	1	1	.50 (30 minutes)	1
203.30(a)(1) and (b)	61,961	12	743,532	.06 (4	44,612

Drug sample requests				minutes)	
203.30(a)(3), (a)(4), (c) Drug sample receipts	61,961	12	743,532	.06 (4 minutes)	44,612
203.31(a)(1) and (b) Drug sample requests	232,355	135	31,367,925	.04 (2 minutes)	1,254,717
203.31(a)(3), (a)(4),(c) Drug sample receipts	232,355	135	31,367,925	.03 (2 minutes)	941,038
203.37(a) Falsification of records	50	4	200	.25 (15 minutes)	50
203.37(b) Loss or theft of samples	50	40	2000	.25 (15 minutes)	500
203.37(c) Convictions	1	1	1	1	1
203.37(d) Contact person	50	1	50	.08 (5 minutes)	4
203.39(g) Reconciliation report	1	1	1	1	1
Total					2,285,536

[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	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record-keeping	Total Hours
203.23(a) and (b) Returned drugs	31,676	5	158,380	.25 (15 minutes)	39,595
203.23(c) Returned drugs documentation	31,676	5	158,380	.08 (5 minutes)	12,670
203.30(a)(2) and 203.31(a)(2) Practitioner verification	2,208	100	220,800	.50 (30 minutes)	110,400
203.31(d)(1) and (d)(2) Inventory record and reconciliation report	2,208	1	2,208	40	88,320
203.31(d)(4) Investigation of discrepancies and losses	442	1	442	24	10,608
203.31(e) Representatives lists	2,208	1	2,208	1	2,208
203.34 Administrative systems	90	1	90	40	3,600
203.37(a) Falsification of drug sample records	50	4	200	6	1200
203.37(b) Loss or theft of drug samples	50	40	2000	6	12,000
203.39(d) Destroyed or	65	1	65	1	65

returned drug samples					
203.39(e) Donated drug samples	3,221	1	3,221	.50 (30 minutes)	1,611
203.39(f) Distribution of donated drug samples	3,221	1	3,221	8	25,768
203.39(g) Drug samples donated to charitable institutions	3,221	1	3,221	8	25,768
203.50(a) Drug origin statement	125	100	12,500	.17 (10 minutes)	2,125
203.50(b) Drug origin statement retention	125	100	12,500	.50 (30 minutes)	6,250
203.50(d) Authorized distributors of record	691	1	691	2	1,382
Total					343,570

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

Dated: February 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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