SUPPORTING STATEMENT
Prescription Drug Marketing Act of 1987
Administrative Procedures, Policies, and Requirements
21 CFR Part 203
0910-0435

Justification

1. Circumstances Making the Collection of Information Necessary

FDA is requesting OMB approval under the Paperwork Reduction Act (44 USC 3501-3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Pub. L. 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 because 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.

2. Purpose and Use of the Information Collection

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

(1) To ban the reimportation of prescription drugs produced in the U.S., 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;

(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.

3. Use of Improved Information Technology and Burden Reduction

The rule incorporates part 11 of the Agency's regulations as well as related guidance for industry in “Part 11, Electronic Records; Electronic Signatures — Scope and Application,” and permits the use of electronic records, electronic signatures, and handwritten signatures executed to electronic records (either alone or in combination with paper records) to create and maintain required records and signatures.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection required as a result of 21 CFR 203 does not duplicate any other information collection. The requirements are specifically mandated by the Prescription Drug Marketing Act of 1987.

5. Impact on Small Businesses or Other Small Entities

In developing these regulations, the Agency took several steps to minimize the economic impact on small entities. The Agency reduced or eliminated several of the requirements under

the proposed rule. The inventory of drug samples held by sales representatives were proposed to be conducted by an executive other than the representative or the immediate supervisor. Comments on the proposal emphasized the costliness of this requirement, indicating it was time consuming and entailed travel expenses to regional sales offices. In response to these comments, the final rule allowed sales representatives and their supervisory personnel to conduct the inventory and reconciliation functions. Also, in response to the comments, FDA reduced the administrative burden associated with the donation of prescription drug samples to charity. Furthermore, FDA found it unnecessarily burdensome to require that lot or control numbers appear on drug sample records, receipts, and reconciliation reports, as proposed. Therefore, the final rule added flexibility by allowing the recording of lot or control numbers on other types of records. Also, in response to comments, the Agency allowed the use of adhesive stickers on retail units to designate a sample unit as a sample. The final rule reduced the drug sample record retention period, which was proposed as 3 years from the sample expiration date. The Agency decided that retention of drug sample records for 3 years from the date of their creation is sufficient for recall facilitation and proper accountability over sample distribution. The Agency analyzed each of the requirements of the final rule and determined that all of them are necessary to ensure that misbranded, adulterated, or expired pharmaceuticals are not distributed to consumers. In addition, the license verification requirement was added in response to comment. The Agency determined that this requirement was important to meet the objectives of PDMA, and that the per-company costs associated with it are expected to decline with new verification methodology. To add flexibility, the final rule permitted the electronic transmission and storage of all paperwork and forms.

6. Consequences of Collecting the Information Less Frequently

Congress intended that PDMA will protect the public against the threat of subpotent, adulterated, counterfeit, and misbranded drugs posed by the existence of drug diversion schemes and a drug diversion submarket, and the absence of appropriate controls over and creation and maintenance of appropriate records regarding the distribution of prescription drugs. Accordingly, the scope and frequency of the requirements is important to establish procedures and requirements pertaining to the reimportation and wholesale distribution of prescription drugs; the sale, purchase, or trade of prescription drugs by hospitals, health care entities, and charitable institutions; and the distribution of prescription drug samples.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no inconsistencies with this provision.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of June 6, 2011 (76 FR 32362), FDA published a 60-day notice requesting comments on the information collection. We received one comment. The comment did not pertain to the information collection discussed in the June 2011 Federal Register notice, but commended the use of electronic and automated health information solutions to reduce costs and improve health care efficiency.

FDA Response:

There were no issues raised in the comment to be resolved.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention of providing any payment or gift to

respondents under these requirements.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under these requirements is protected under 21 CFR part 20. The unauthorized use or disclosure of trade secrets is specifically prohibited under section 310(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12a. Estimates of Annualized Hour Burden

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Respondents	Average Burden per Response (in hours)	Total Hours
203.11	1	1	1	.5	1
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	2000	.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 Reporting Burden Hours			**2,285,536**		

Table 2.--Estimated Annual Recordkeeping Burden					
21 CFR Section	**Number of Recordkeepers**	**Number of Records per Recordkeeper**	**Total Annual Records**	**Average Burden per Recordkeeping (in hours)**	**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	1200
203.37(b)	50	40	2000	6	12,000
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	.50	1,611
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	1,382
Total Recordkeeping Burden Hours:			**343,570**		

12b. Annualized Cost Burden Estimate

FDA's Economics Staff estimates an average industry wage rate of approximately $75 per hour for preparing and submitting the information collection requirements under 21 CFR 203. Using this wage rate, and multiplied times the total hour burden estimated above (2,285,536 + 343,570 X $75), the total cost burden to respondents is $197,182,950.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no other costs, including operating and maintenance costs or capital costs, associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA estimates that 3 FTE's are required to review reports and to inspect records resulting from the regulation. If each FTE costs $160,000, the total cost to the Federal Government will be $480,000.

15. Explanation for Program Changes or Adjustments

There are no changes in burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish tabulated results of these information collection requirements.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no forms associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.