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

Justification

1. Circumstances of Information Collection

The Food and Drug Administration (FDA) is requesting OMB approval under the Paperwork Reduction Act (44 USC 35) 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 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 American goods returned causing a health and safety risk to American 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 American 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),(b)	Drug sample requests (drug samples distributed by mail or common carrier).
21 CFR 203.30(a)(3),(a)(4),(c)	Drug sample receipts (receipts for drug samples distributed by mail or common carrier).
21 CFR 203.31(a)(1),(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),(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 203.38(a)	Printing lot or control numbers on the drug sample unit label.
21 CFR 203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.
21 CFR 203.50(a)	Drug origin statement.

RECORDKEEPING REQUIREMENTS

21 CFR 203.23(a),(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 to prescribe the product.
21 CFR 203.31(d)(1),(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.
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. <u>Purpose and Use of Information</u>

The reporting and recordkeeping requirements in the final regulations 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 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 samples in writing;
(5) To mandate storage, handling, and recordkeeping requirements for 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

The final rule incorporates part 11 of the agency's regulations 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. An electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, maintained, archived, retrieved, or distributed by a computer system. Use of photographic records and electrographic records, such as records maintained on microfilm, microcard, microfiche, and xerographic copies, is also permitted under the final rule. The agency believes that the use of these types of media will provide industry with a high degree of flexibility in designing recordkeeping systems that use of such systems will result in greater efficiency and lower costs for industry than paper based systems.

4. Efforts to Identify Duplication

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. Involvement of Small Entities

In developing the final rule, 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. Under the proposal, the inventory of drug samples held by sales representatives would be conducted by an executive other than the representative or the immediate supervisor. Comments 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 allows sales representatives and their supervisory personnel to conduct the inventory and reconciliation functions. Also, in response to comments on the proposal, 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 adds flexibility by allowing the recording of lot or control numbers on other types of records. Also, in response to comments, the agency is allowing the use of adhesive stickers on retail units to designate a sample unit as a sample. The final rule reduces 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 permits the electronic transmission and storage of all paperwork and forms.

6. Consequences If Information Collected 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. Consistency with the Guidelines in 5 CFR 1320.6

There are no inconsistencies with this provision.

8. Consultation Outside the Agency

In the Federal Register of September 13, 1988, FDA published proposed State licensing guidelines to implement that part of the new law. FDA received approximately 50 comments on the proposal. In the Federal Register of September 14, 1990, after considering all the comments received on the proposed rule, FDA published revised State licensing guidelines as a final rule.

On August 1 and November 3, 1988, and January 26, 1990, FDA issued letters to the regulated industry and other interested persons providing information and guidance on PDMA. The letters requested suggestions from the public regarding the drafting of regulations. Suggestions from the public were made part of a public docket. The agency received requests for the issuance of further guidance to provide specific information in certain areas and to answer particular questions.

In the Federal Register of March 14, 1994 (59 FR 11842), FDA issued a proposed rule to set forth agency policies and requirements for those sections of the PDMA not related to State licensing of wholesale distributors. The proposal contained

provisions on prescription drug reimportation, wholesale distribution of prescription drugs by unauthorized distributors, the resale of prescription drugs by hospitals, health care entities, and charitable institutions, and distribution of prescription drug samples. The proposal called for the submission of comments by May 30, 1994 but, at the request of certain individuals, the comment period was extended by notice in the Federal Register to August 15, 1994.

FDA received 56 comments on the proposed rule from prescription drug manufacturers, industry organizations, professional associations and organizations, law enforcement agencies, and others. Although most of the comments addressed only specific provisions of the rule, a few commented generally on the proposed rule, and those comments were mixed. For example, one comment stated that it "supports the controls on prescription drug samples sought through the passage of the PDMA and feels that, in general, the proposed rule is a positive step in combating the market in diverted prescription drugs and ensuring consumers that drug products continue to remain safe and effective." Another comment, however, stated that "finalization of the proposed rule will create unnecessary additional administrative burdens for companies and their sales representatives" and "would not improve significantly the industry's ability to track sample distribution and reduce the possibility of diversion of samples."

A large number of comments addressed the provisions of the proposed rule relating to sample distribution. In fact, comments were received on almost all of the sections of the proposed rule dealing with sample distribution. Most of these comments were critical of the manner in which the agency proposed to implement the sample distribution requirements contained in PDMA. In addition to comments on sample distribution, comments were received on sections of the proposed rule relating to reimportation of prescription drugs, resales of prescription drugs purchased by health care entities, recordkeeping and investigation requirements, and wholesale distribution.

Although the proposed rule provided a 60-day comment period under the Paperwork Reduction Act of 1980, and this final rule responds to the comments received, FDA is providing an additional opportunity for public comment under the Paperwork Reduction Act of 1995, which became effective after the expiration of the comment period and applies to this final rule.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under these requirements.

10. Assurance of Confidentiality

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 Act.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

Estimated Annual Reporting Burden

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.11	12	1	12	.5	6
203.30(a)(1); (b)	61,961	12	743,532	.06	44,612
203.30(a)(3) & (a)(4); (c)	61,961	12	743,532	.06	44,612
203.31(a)(1); (b)	232,355	135	31,367,925	.04	1,254,717
203.31(a)(3) & (a)(4); (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
203.38(a)	2,208	1	2,208	3.00	6,624
203.39(g)	3,221	1	3,221	2.00	6,442
203.50(a)	125	100	12,500	.08	1,000
				Total Reporting Burden Hours:	2,300,628

Estimated Annual Recordkeeping Burden

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.23(a); (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2); 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) & (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
203.38(b)	2,208	14,543	32,111,457	.02	642,229
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)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2.00	1,382
				Total Recordkeeping Burden Hours:	1,061,368

Note: There are no operating and maintenance costs or capital costs associated with this collection of information.

13. Estimates of Annualized Cost Burden to Respondents

FDA's Economics Staff estimates an average industry wage rate of $50.00 per hour for preparing and submitting the information collection requirements under 21 CFR 203. This figure is an average of the following wage rates (based on the percentage of time required for each type of employee): Upper management at $70.00 per hour; middle management at $35.00 per hour; and clerical assistance at $23.00 per hour. Using the averaged wage rate of $50.00 per hour, and multiplied times the total hour burden estimated above (2,300,628 + 1,061,368 = 3,361,996), the total cost burden to respondents is $168,099,800.

14. Estimates of Annualized Cost Burden to the Government

FDA estimates 10 FTE's will be required to review reports and to inspect records resulting from the regulation. If each FTE costs $100,000, the total cost to the Federal Government will be $1,000,000.

15. Changes in Burden

This is a final rule and the information collection will be effective according to the implementation plan in the final rule.

16. Time Schedule, Publication and Analysis Plans

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

17. Exemption for Display of Expiration Date

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 for Paperwork Reduction Act Submissions" of form OMB 83I.