

UNITED STATES FOOD & DRUG ADMINISTRATION

Prescription Drug Marketing

21 CFR Part 203

OMB Control No. 0910-0435

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Specifically, the Federal Food, Drug, and Cosmetic Act (FD&C Act, the act), as amended by the Prescription Drug Marketing Act of 1987 (PDMA) and Prescription Drug Amendments of 1992, establishes requirements for the reimportation and wholesale distribution of prescription drugs; the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples. Because insufficient safeguards existed over 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, PDMA was enacted. PDMA is 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. Requirements under PDMA are codified at 21 CFR Part 203: *Prescription Drug Marketing*.

The regulations in 21 CFR Part 203 include reporting and recordkeeping requirements 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 healthcare 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; and (6) to prohibit, with certain exceptions, the sale, purchase, or trade, or the offer to sell, purchase, or trade, of prescription drugs that were purchased by hospitals or other healthcare entities or that were donated or supplied at a reduced price to a charitable organization.

We therefore request extension of OMB approval for the information collection provisions set forth under 21 CFR Part 203 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the Part 203 regulations is to implement the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992, except for those sections relating to State licensing of wholesale distributors (see 21 CFR Part 205), to protect the public health, and to protect the public against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples. The regulatory requirements provide for records and reports that FDA evaluates to determine compliance with the regulations.

Respondents: Respondents to the information collection are persons or entities engaged in prescription drug marketing as described in FDA regulations at 21 CFR Part 203.

3. Use of Improved Information Technology and Burden Reduction

The regulations incorporate by reference Part 11 regulatory requirements, as well as related guidance for industry entitled “*Part 11, Electronic Records; Electronic Signatures — Scope and Application,*” permitting 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. The regulations otherwise prescribe no specific requirements regarding the means by which reporting and recordkeeping is to be satisfied. Respondents are free to choose whatever methods they find most preferable and we anticipate all will utilize electronic technology to do so.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While FDA has established information collections to support other agency regulations, this information collection specifically covers provisions found in 21 CFR 203 implementing prescription drug marketing requirements mandated by the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

The regulatory requirements are intended to protect the public health and apply equally to all respondents. However, we do not believe the requirements impose undue burden on small entities. Rather, we believe the information collection requirements are the minimum necessary to ensure the safety and effectiveness of human drug products covered by the regulations. At the same time, we assist small businesses in complying with our regulations through contact with scientific and administrative staffs within the agency. A Small Business Guide is also available on our website at <http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm>.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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 March 12, 2021 (86 FR 14128), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

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.

12. Estimates of Annualized Hour Burden

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section/Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
203.11--Reimportation	1	1	1	0.5	1
203.37(a)--Falsification of records	140	21.4	3,000	0.25	750
203.37(b)--Loss or theft of samples	140	178.57	25,000	0.25	6,250
203.37(c)--Convictions	1	1	1	1	1
203.37(d)--Contact person	20	1	20	0.08	5
203.39(g)--Reconciliation report	1	1	1	1	1
Total			0		0

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

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
203.23(a) and (b)--Returned drugs	2,200	71.9909	158,380	0.25	39,595
203.23(c)--Returned drugs storage documentation	2,200	71.9909	158,380	~0.08	12,670
203.30- 203.39; documentation regarding sample distribution	140	202	28,280	~ .07-.08	2,121
Total			0		0

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

Based on a review of Agency data, we assume 2,200 respondents may incur burden resulting from the information collection activity associated with the requirements in § 203.23(a) through (c). A total of 140 pharmaceutical companies have submitted information on drug sample distribution under part 203. Those same respondents also have recordkeeping requirements under part 203. These estimates reflects our assumption of the average burden per recordkeeping on all respondents.

12b. Annualized Cost Burden Estimate

We estimate an average industry wage rate of approximately \$85 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 Costs to Respondents and Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

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 \$275,000, the total cost to the Federal Government will be \$825,000.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. Since last renewal we have adjusted our estimate of the overall burden downward to reflect a decrease of 2,567,562 hours and 64,432,231 records annually. This reflects the removal of burden associated with provisions in 21 CFR Part 203 that are no longer in effect following enactment of the Drug Supply Chain Security Act (DSCSA). The agency is currently in the process of making corresponding changes to the regulations (0910-AH56). At the same time, upon preparation for our submission we noted a line item pertaining to reconciliation reports under 21 CFR 203.39 was inadvertently omitted. While we have not received any such reports, the information collection is provided for in the regulations and we retain the 1 hour of annual burden and 1 annual response in the event such submissions are received.

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.