U.S. Food & Drug Administration

Prescription Drug Marketing Regulations:
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), 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*.

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 accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of December 14, 2017 (82 FR 58808). One caller responded to the notice asking about the impact the Drug Supply Chain Security Act (DSCSA) has on the information collection. We noted that we are currently proposing to amend our regulations at

21 CFR Part 203 to reflect changes resulting from enactment of the DSCSA (RIN 0910-AH56). We also noted that upon finalization of rulemaking we will revise the information collection accordingly and expect it will result in a reduction of burden to respondents.

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 Burden[1]

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
203.30(a)(1) and (b)--Drug sample requests	61,961	12	743,532	0.06	44,612
203.30(a)(3), (a)(4), and (c)--Drug sample receipts	61,961	12	743,532	0.06	44,612
203.31(a)(1) and (b)--Drug sample requests	232,355	135	31,367,925	0.04	1,254,717
203.31(a)(3), (a)(4), and (c)--Drug sample receipts	232,355	135	31,367,925	0.03	941,038
203.37(a)--Falsification of records	50	4	200	0.25	50
203.37(b)--Loss or theft of samples	50	40	2,000	0.25	500
203.37(c)--Convictions	1	1	1	1	1
203.37(d)--Contact person	50	1	50	0.08	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/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	31,676	5	158,380	0.25	39,595
203.23(c)--Returned drugs documentation	31,676	5	158,380	0.08	12,670
203.30(a)(2) and 203.31(a)(2)--Practitioner verification	2,208	100	220,800	0.5	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	1,200
203.37(b)--Loss or theft of drug samples	50	40	2,000	6	12,000
203.39(d)--Destroyed or returned drug samples	65	1	65	1	65
203.39(e)--Donated drug samples	3,221	1	3,221	0.5	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	0.17	2,125
203.50(b)--Drug origin statement retention	125	100	12,500	0.5	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.

Based on a review of Agency data, we retain the currently approved burden estimate for the information collection, as reflected in Tables 1 and 2 above. This assumes 7,500 respondents to the information collection, based on a cumulative number of entities as described in our final rule of December 3, 1999 (64 FR 67720).

12b. Annualized Cost Burden Estimate

FDA's Economics Staff estimates 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

There are no program changes or adjustments associated with this extension. However, we have consolidated the ICs previously appearing at www.reginfo.gov as itemized and associated with the individual regulatory requirements into either reporting or recordkeeping. Also, and as noted previously under *Question 8*, upon finalization of agency rulemaking amending 21 CFR Part 203 (RIN 0910-AH56), we will revise the information collection accordingly.

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.