U.S. FOOD & DRUG ADMINISTRATION

Prescription Drug Marketing

OMB Control No. 0910-0435 - Extension

SUPPORTING STATEMENT

Terms of Clearance *– Terms continue: Approved consistent with the understanding that, upon finalization of any agency rulemaking amending 21 CFR Part 203 (see RIN 0910-AH56), FDA will submit a request to revise the information collection accordingly.*

We discuss rulemaking 0910-AH56 and its impact on the information collection at Q-15 below.

SUPPORTING STATEMENT - **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection helps support Food and Drug Administration (FDA, us or we) regulations and statutory requirements that govern prescription drug marketing. Specifically, the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug Marketing Act of 1987 (Pub. L. 100-293) (PDMA) and Prescription Drug Amendments of 1992, establishes requirements for the: (1) reimportation and wholesale distribution of prescription drugs; (2) 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 (3) 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. Agency regulations implementing PDMA requirements are codified in **21 CFR part 203**.

The regulations in part 203 include reporting and recordkeeping requirements intended to help achieve the following goals to: (1) 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) ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) 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) require licensed or authorized practitioners to request prescription drug samples in writing; (5) mandate storage, handling, and recordkeeping requirements for prescription drug samples; and (6) 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 are requesting 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 PDMA and the Prescription Drug Amendments of 1992 is to protect the public health against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples. The information collection helps FDA determine compliance with the applicable requirements.

The information collection includes applications for reimportation to provide emergency medical care, investigations by manufacturers or authorized distributors of potential falsification of drug sample records, notification of distribution of drug samples and any loss or theft of drug samples, notification of convictions for violation of section 503(c)(1) of the Act involving the sale, purchase, or trade of drug samples, notification of the individual responsible for drug sample information and FDA reconciliation reports. In addition, any returns of drugs must be documented and stored appropriately for return to the manufacturer or wholesale distributor, to prevent abuse or exploitation of the distribution system.

3. Use of Improved Information Technology and Burden Reduction

As communicated in the regulations, if requirements of 21 CFR part 11 are met, electronic records may be used as an alternative to paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA, PDA, or this part. The regulations otherwise prescribe no specific requirements regarding the means by which reporting and recordkeeping are to be satisfied. Respondents are free to choose whatever methods they find most preferable, and we anticipate all respondents will use electronic technology to do so.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We believe the information collection poses no undue burden on small entities. 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 applicable statutory and regulatory requirements.

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

There are no special circumstances for the collection of information.

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

We published a 60-day notice for public comment in the *Federal Register* of January 22, 2024 (89 FR 3928) on the proposed collection of information. Although one comment was received, it was not responsive to the four information collection topics solicited under 5 CFR 1320.8(d). A second comment was received subsequent to FDA's submission of the ICR to OMB. The comment appears to support the need for regulation regarding prescription drug sample distribution and suggests that FDA find alternative means for implementation of current requirements, but offers no specific examples. The comment also refers to "*proposed*" regulations, and so we are clarifying that the information collection is intended to cover the scope of activity as currently set forth in 21 CFR 203.1: *procedures and requirements pertaining to the reimportation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples.* We appreciate this comment, but have made no changes to our current estimates. We continue to evaluate efficiencies for the information collection that would maximize our limited resources while imposing least burdensome practices on respondents. In 2019 FDA established a Data Modernization Action Plan, as posted to our website at https://www.fda.gov/about-fda/reports/data-modernization-action-plan, which provides information regarding these ongoing efforts across the agency.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii), data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted is *name, email address,* and *telephone number*. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Hour Burden

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

12a. Annualized Hour Burden Estimate

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

21 CFR Section; Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 203.11; reimportation	1	1	1	0.5 (30 mins.)	0.5
§ 203.37(a); falsification of records	140	2.14	300	0.25 (15 mins.)	75
§ 203.37(b); loss or theft of samples	140	57.14	8,000	0.25 (15 mins.)	2,000
§ 203.37(c); convictions	1	1	1	1	1
§ 203.37(d); contact person	20	1	20	0.08 (5 mins.)	2
§ 203.39(g); reconciliation report	1	1	1	1	1
Total			8,323		2,080

[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; Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart C: Sale restrictions					
§ 203.23(a) and (b); returned drugs	2,200	71.99	158,380	0.25 (15 mins.)	39,595
§ 203.23(c); returned drugs storage documentation	2,200	71.99	158,380	0.08 (5 mins.)	12,670
Subpart D: Samples					

21 CFR Section; Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§§ 203.30 – 203.39; documentation regarding sample distribution	140	46,716.67	6,540,334	0.08 (5 mins.)	523,227
Total			0		575,492

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

We assume 140 pharmaceutical companies report information to FDA in compliance with regulations in 21 CFR part 203, and include burden that may be attendant to associated recordkeeping in our estimate. The estimates in Table 1 reflect a decrease of 19,700 responses and 4,928 hours since our last evaluation with regard to the volume of loss/theft/falsification reports received under 21 CFR § 203.37 over the past 18 months. Additionally, based on a review of agency data, we estimate 2,200 respondents may incur burden resulting exclusively from recordkeeping requirements established in 21 CFR part 203.

Under 21 CFR 203.38(b), implemented for PDMA, a manufacturer or authorized distributor is required to maintain records of drug sample distribution for all samples distributed under section 503(d)(2) or 503(d)(3) of the FD&C Act that are sufficient to permit tracking of sample units to the point of the licensed practitioner. The PDMA does not require manufacturers and distributors to *report* the number of drug sample requests they receive to FDA. Instead, manufacturers and distributors are only required to maintain reports and other records relating to the distribution of drug samples and to make those reports available to FDA within 2 business days of an FDA request.

After the enactment of section 6004 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) (effective October 2012), manufacturers and authorized distributors are required to collect and maintain the identity and quantity of drug samples requested, among other information, and must now annually submit the required information, aggregated as specified under PDMA, to FDA via the Electronic Submissions Gateway, the database where manufacturers and authorized distributors are required to submit the drug sample data.

12b. Annualized Cost Burden Estimate

To calculate cost burden we assume an average industry wage rate of $88.70 per hour (averaged from wages for marketing managers under occupation code: 11-2021 as reported by the U.S. Department of Labor, Bureau of Labor Statistics: May 2022 National Occupational Employment and Wage Estimates, available at https://www.bls.gov/oes/current/naics4_325400.htm). Included in our estimate is the time we believe is needed to document and submit information as required by 21 CFR 203. Using this wage rate, we multiplied the total hour burden hours and calculated ((2,080+575,492)) x $88.70), an annual cost of $51,230,636.40.

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

We allocate three (3) full-time equivalents (FTE) to review reports and inspect records as required by the applicable regulations. Assuming fully-loaded costs of $336,269 per one FTE (salary plus overhead, full-time 40-hour week), we calculate total annual costs to the Federal Government to be $1,008,807 ($336,269 x 3).

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. Since last renewal, we have adjusted our estimate of the overall burden to reflect an increase of 6,512,054 responses and 520,956 hours annually attributable to recordkeeping for drug samples under 21 CFR part 203 subpart D. Because current implementation of requirements under the Drug Supply Chain Security Act (currently approved in OMB control no. 0910-0806) apply to ***manufacturers***, ***wholesalers***, and ***dispensers*** as well as ***distributers***, we have considered that current recordkeeping requirements for drug samples under 21 CFR part 203 may apply to more respondents. To account for this activity, we increased the number of responses and hours per each of the 140 pharmaceutical companies identified in Row 3 of Table 2 in Q-12 above *("§§ 203.30 – 203.39; documentation regarding sample distribution*"), and have included it with the other recordkeeping elements.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.