4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5451]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with Agency regulations that govern prescription drug marketing.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-5451 for "Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-976-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements--21 CFR Part 203

OMB Control Number 0910-0435--Extension

This information collection helps support FDA regulations. 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 healthcare 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. Requirements under PDMA are codified at part 203 (21 CFR part 203), Prescription Drug Marketing.

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.

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

We estimate 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	Total Hours[2]

§ 203.11; Reimportation	1	1	1	0.5 (30 minutes)	0.5
§ 203.37(a); Falsification of records	140	2.14	300	0.25 (15 minutes)	75
§ 203.37(b); Loss or theft of samples	140	57.14	8,000	0.25 (15 minutes)	2,000
§ 203.37(c); Convictions	1	1	1	1	1
§ 203.37(d); Contact person	20	1	20	0.08 (5 minutes)	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 Activity	Number of Recordkeepers	Number 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 minutes)	39,595
§ 203.23(c); Returned drugs storage documentation	2,200	71.99	158,380	0.08 (5 minutes)	12,670
Subpart D: Samples					
§§ 203.30 to 203.39; documentation regarding sample distribution	140	46,716.67	6,540,334	0.08 (5 minutes)	523,227
Total			6,857,094		575,492

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

Based on a review of Agency data, since our last request for OMB approval, we have adjusted our estimate of 1 burden to reflect an increase of 6,492,354 responses and 516,028 hours annually. The estimates in table 1 (a decrease of 19,700 responses and 4,928 hours since the last OMB approval) reflect an assessment of the volume of loss/theft/falsification reports received by the Agency under § 203.37 over the past 18 months. While the requirements have not changed, we believe this more accurately reflects the number of reports estimated to be submitted to FDA under this section. Our adjustments to table 2 are attributable to a more accurate reflection of the number of drug sample requests received by manufacturers and authorized distributors of record. The PDMA does not require manufacturers and distributors to report the number of drug sample requests they receive to FDA. However, section 6004 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) requires that manufacturers and authorized distributors submit to FDA annually the identity and quantity of drug samples requested, among other information.

Dated: January 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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