TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
507.7(e)(1); change labels on products with labels	1,526	4	6,104	1	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	1,329	1	1,329	1	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	330	312	102,960	0.01 (36 seconds)	1,030
507.28(b); holding and distribution of human food byproducts for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					29,687

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

These figures are based on our regulatory impact analysis in support of the final rule on Preventive Controls for Food for Animals, which published in the **Federal Register** of September 17, 2015 (80 FR 56170). Using Agency data we estimated the number of animal food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: May 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11114 Filed 5–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 25, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

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, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing Act of 1987—Administrative Procedures, Policies, and Requirements

OMB Control Number 0910–0435—Extension

This information collection supports FDA regulations codified at part 203 (21 CFR part 203) implementing the Prescription Drug Marketing Act of 1987 (PDMA). The PDMA was intended to ensure safe and effective drug products and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold to consumers. The reporting and recordkeeping requirements found in the 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 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; (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; and (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.

In the **Federal Register** of December 14, 2017 (82 FR 58808), we published a notice soliciting public comment of the information collection. One caller responded to the notice asking about the impact the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality Security Act of 2013) has on the information collection. We note that the Agency is currently proposing to amend its regulations at part 203 to reflect changes resulting from enactment of the DSCSA (RIN 0910–AH56). While we expect these changes will result in a reduction of burden associated with the information collection, current regulations and associated information collection requirements remain in effect. Upon finalization of rulemaking, we will revise the information collection accordingly.

We therefore estimate the burden for the information collection 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
203.11—Reimportation	1	1	1	0.5 (30 minutes)	1
203.30(a)(1) and (b)—Drug sample requests	61,961	12	743,532	0.06 (4 minutes)	44,612
203.30(a)(3), (a)(4), and (c)—Drug sample receipts	61,961	12	743,532	0.06 (4 minutes)	44,612
203.31(a)(1) and (b)—Drug sample requests	232,355	135	31,367,925	0.04 (2.5 minutes)	1,254,717
203.31(a)(3), (a)(4), and (c)—Drug sample receipts	232,355	135	31,367,925	0.03 (2 minutes)	941,038
203.37(a)—Falsification of records	50	4	200	0.25 (15 minutes)	50
203.37(b)—Loss or theft of samples	50	40	2,000	0.25 (15 minutes)	500
203.37(c)—Convictions	1	1	1	1	1
203.37(d)—Contact person	50	1	50	0.08 (5 minutes)	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	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
203.23(a) and (b)—Returned drugs	31,676	5	158,380	0.25 (15 minutes)	39,595
203.23(c)—Returned drugs documentation	31,676	5	158,380	0.08 (5 minutes)	12,670
203.30(a)(2) and 203.31(a)(2)—Practitioner verification	2,208	100	220,800	0.5 (30 minutes)	110,400
203.31(d)(1) and (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 (30 minutes)	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 (10 minutes)	2,125
203.50(b)—Drug origin statement retention	125	100	12,500	0.5 (30 minutes)	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.

Dated: May 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11113 Filed 5–23–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0412]

Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax.'' The purpose of this guidance is to assist sponsors in the development of new drugs for the prophylaxis of inhalational anthrax. This guidance finalizes the draft guidance of the same name issued on February 16, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on May 24, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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