requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Report

Report title: Reporting Requirements Associated with Regulation XX Concentration Limit; Financial Company (as defined) Report of Consolidated Liabilities.

Agency form number: FR XX; FR XX–1.

OMB control number: 7100–0363.

Frequency: Event-generated; annual.

Respondents: Insured depository institutions, bank holding companies, foreign banking organizations, savings and loan holding companies, companies that control insured depository institutions, and nonbank financial companies supervised by the Board; U.S. and foreign financial companies that do not otherwise report consolidated financial information to the Board or other appropriate Federal banking agency.

Estimated number of respondents: FR XX (Section 251.4(b)): 1; FR XX (Section 251.4(c)): 1; FR XX–1: 43.

Estimated average hours per response: FR XX (Section 251.4(b)): 10, FR XX (Section 251.4(c)): 10; FR XX–1: 2.

Estimated annual burden hours: FR XX (Section 251.4(b)): 10; FR XX (Section 251.4(c)): 10; FR XX–1: 86 (106 total).

General description of report: The Board adopted Regulation XX to implement section 14 of the Bank Holding Company Act of 1956 (BHC Act), which was added by section 622 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). Section 14 established a financial sector concentration limit that generally prohibits a financial company from merging or consolidating with, or otherwise acquiring, another company if the resulting company's liabilities upon consummation would exceed 10 percent of the aggregate liabilities of all financial companies. Regulation XX established certain reporting requirements for financial companies. The Board created the FR XX–1 reporting form to collect information required to be submitted by Regulation XX.

Legal authorization and confidentiality: This information collection is authorized by section 14 of the Bank Holding Company Act (12 U.S.C. 1852(d)) and Regulation XX (12 CFR part 251). The obligation of financial companies to comply with the consolidated liabilities reporting requirement is mandatory. Compliance by financial companies with the transactional reporting requirements is required in order to obtain the benefit of Board consent to consummation of the transactions.

Section 251.6 and FR XX–1. As noted, the required reporting of calendar year-end liabilities under section 251.6 of Regulation XX can be satisfied by many financial companies through their continued reporting of consolidated financial information to the Board or other appropriate Federal banking agency though the various reports listed above. The information collected on those forms has been the subject of separate authorization and confidentiality determinations. With regard to the collection of the specific information at issue, calendar year-end liabilities (including as collected on the FR XX–1), such information generally is not considered confidential, but some information, depending on the circumstances, may be the type of confidential commercial and financial information that may be withheld under exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C 552(b)(4)). As required information, it may be withheld under exemption 4 on a case-by-case basis only if public disclosure could result in substantial competitive harm to the submitting institution. Any request from a submitter for confidential treatment should be accompanied by a detailed justification for confidentiality.

Section 251.4. The information collected under section 251.4 (under both its prior written consent provision for individual transactions and the general consent authority) consists of (1) a description of the acquisition and (2) the change in and resultant aggregate amount of financial company liabilities. The reported liabilities information, in like fashion to the liabilities information reported under section 251.6, generally is not considered confidential but, depending on the circumstances, may be the type of confidential commercial and financial information that may be withheld under exemption 4 of FOIA. The description of the individual acquisitions provided under the prior written consent provisions generally would not be deemed confidential, but that some such information may be of the type that could be withheld under exemption 4 on a case-by-case basis, under the standards enumerated above.

Current actions: On August 16, 2017, the Board published a notice in the **Federal Register** (82 FR 38906) requesting public comment for 60 days on the extension, without revision, of the FR XX and FR XX–1. The comment period for this notice expired on October 16, 2017. The Board did not receive any comments. The information collection will be extended as proposed.

Board of Governors of the Federal Reserve System, December 11, 2017.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2017–26962 Filed 12–13–17; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 the information collection in the regulations on the Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements.

DATES: Submit either electronic or written comments on the collection of information by February 12, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must

be submitted on or before February 12, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2011–N–0279 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing Act of 1987; 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.

- 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.gpo.gov/fdsys/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.

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: Under the PRA (44 U.S.C. 3501–3520), 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 Act of 1987—Administrative Procedures, Policies, and Requirements

OMB Control Number 0910–0435—Extension

This information collection supports FDA regulations. Specifically, regulations codified at 21 CFR part 203 implement 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 tables below we have listed specific regulatory provisions that include information collection.

We estimate the burden of 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 (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	Number of recordkeepers	Number 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 the information collection, we have retained the currently approved estimated burden.

Dated: December 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26933 Filed 12–13–17; 8:45 am]

BILLING CODE 4164–01–P