comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
111.14, records of personnel practices, including documentation of training	15,000	4	60,000	1	60,000
111.23, records of physical plant sanitation practices, including pest control and water quality	15,000	1	15,000	0.2	3,000
111.35, records of equipment and utensils calibration and sanitation practices	400	1	400	12.5	5,000
111.95, records of production and process control systems	250	1	250	45	11,250
111.140, records that quality control personnel must make and keep	240	1163	279,120	1	279,120
111.180, records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement	240	1163	279,120	1	279,120
111.210, requirements for what the master manufacturing record must include	240	1	240	2.5	600
111.260, requirements for what the batch record must include	145	1408	204,160	1	204,160
111.325, records that quality control personnel must make and keep for laboratory operations	120	1	120	15	1,800
111.375, records of the written procedures established for manufacturing operations	260	1	260	2	520
111.430, records of the written procedures for packaging and labeling operations	50	1	50	12.6	630
111.475, records of product distribution and procedures for holding and distributing operations	15,000	1	15,000	0.4	6,000
111.535, records for returned dietary supplements	110	4	440	13.5	5,940
111.570, records regarding product complaints	240	600	144,000	0.5	72,000
Total					929,140

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

The average burden per recordkeeping estimates in table 1 are based on those in the June 25, 2007, final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute in the ''Survey of Manufacturing Practices in the Dietary Supplement Industry'' cited in that rule.

The estimates in table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehousers that reported in the survey that they have not established written standard operating procedures or do not maintain records that were later required by the June 25, 2007, final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehousers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, ''What must the batch production record include?'' The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260 (what the batch record must include).

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04014 Filed 2–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Act Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 paperwork burden of requesting a waiver or reduction of fees under Animal Drug User Fee Act (ADUFA).

DATES: Submit either electronic or written comments on the collection of information by April 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Animal Drug User Fees and Fee Waivers and Reductions (OMB Control Number 0910–0540)—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (Pub. L. 108–130) amended the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from, or a reduction of those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled, ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.'' This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA's animal drug user fees. Further, this guidance also describes the types of fees and fee waivers and reductions; what information FDA recommends be submitted in support of a request for a fee waiver or reduction; how to submit such a request; and FDA's process for reviewing requests.

Respondents to this collection of information are new animal drug sponsors. Requests or waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed including application fees, product fees, establishment fees, or sponsor fees.

FDA estimates the burden for 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
740(d)(1)(A); significant barrier to innovation.	45	1 time for each application.	45	2	90
740(d)(1)(B); fees exceed cost	8	3.75	30	0.5 (30 minutes)	15
740(d)(1)(C); free choice feeds	5	1 time for each application.	5	2	10
740(d)(1)(D); minor use or minor species	76	1 time for each application.	76	2	152
740(d)(1)(E); small business	3	1 time for each application.	3	2	6
Request for reconsideration of a decision	2	1 time for each application.	2	2	4
Request for review (user fee appeal officer)	0	1 time for each application.	0	0	0
Total					277

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

Based on FDA's database system, from fiscal year (FY) 2010 to 2012 there were an estimated 173 sponsors subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the average number of submission types received by FDA in FY 2010–2012.

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04013 Filed 2–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1600]

Draft Guidance for Industry and Tobacco Retailers; Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent.'' This draft guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to not substantially equivalent (NSE) orders issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 28, 2014.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for tobacco retailers entitled ''Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent.'' In this draft guidance, FDA provides information on its enforcement policy regarding so-called provisional tobacco products that become subject to NSE orders under the FD&C Act. The provisional products addressed by this draft guidance are tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a section 905(j) (21 U.S.C. 387e(j)) (or substantial equivalent) report was submitted no later than March 22, 2011. Because the FD&C Act permitted this specific group of products to remain on the market pending FDA's review of the report, there will very likely be products at retail locations within the United States when FDA issues an order finding a tobacco product NSE. This draft guidance explains that FDA does not intend to take enforcement action for at least 30 calendar days from the date the NSE order issues for those products that are in the retailer's current inventory at a specific retail location on the date FDA issues the NSE order.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03978 Filed 2–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Loan Repayment Program for Repayment ofHealth Professions Educational Loans

Announcement Type: Initial.

CFDA Number: 93.164.

Key Dates: February 14, 2014 first award cycle deadline date; August 15, 2014 last award cycle deadline date; September 12, 2014 last award cycle deadline date for supplemental loan repayment program funds; September 30, 2014 entry on duty deadline date.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2014 includes $19,090,023 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service as defined in the IHS LRP policy clarifications at *http://www.ihs.gov/loanrepayment/documents/LRP_Policy_Updates.pdf* in Indian health programs.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by 25 U.S.C. 1616a.

II. Award Information

The estimated amount available is approximately $19,090,023 to support approximately 440 competing awards averaging $43,358 per award for a two year contract. One year contract extensions will receive priority