Consultation Policy issued in February 2016.

ADDRESSES: 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sarah Walinsky, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, (240) 402–4075.

SUPPLEMENTARY INFORMATION:

I. Background

Under Executive Order 13175 of November 6, 2000, executive departments and Agencies are charged with engaging in regular and meaningful consultation and collaboration with Indian tribal governments in the development of Federal policies that have tribal implications and are responsible for strengthening the government-to-government relationship between the United States and Indian Tribes. The HHS Tribal Consultation Policy, revised on December 14, 2010, further clarifies that each HHS Operating and Staff Division must have an accountable consultation process to ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications. The FDA Tribal Consultation Policy, which finalizes the draft FDA Tribal Consultation Policy issued in February 2016, is based on the HHS Tribal Consultation Policy and includes Agency-specific consultation guidelines that complement the Department-wide efforts.

The purpose of the FDA Tribal Consultation Policy is to further the government-to-government relationship between FDA and Indian Tribes and facilitate tribal consultation with FDA. The policy provides background on FDA's mission and organizational structure and elaborates on the principles and guidelines in the HHS Tribal Consultation Policy. We consulted with Indian Tribes on the FDA Tribal Consultation Policy, which is intended to serve as a platform for the Agency to create consistent and meaningful tribal consultation across FDA Centers and Offices. A copy of the final policy has also been shared with Indian Tribes in a letter to tribal leaders.

II. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/tribal* or *https://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the document.

Dated: December 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31951 Filed 1–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0118]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the 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 (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 information collection provisions of FDA regulations requiring that the Agency receives prior notice before food is imported or offered for import into the United States.

DATES: Submit either electronic or written comments on the collection of information by March 6, 2017.

ADDRESSES: You may submit comments 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 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2010–N–0118 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management 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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285

OMB Control Number 0910–0520—Revision

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receives prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting the Agency review after FDA has refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(*l*) of the FD&C Act; and § 1.285(i) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, ''any country to which the article has been refused entry.''

Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain additional information that indicates prior refusals by any country and also identifies the country or countries, the Agency may better identify imported food shipments that may pose safety and security risks to U.S. consumers. This additional knowledge can further help FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States.

Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *http://www.access.fda.gov/.* Information the Agency collects in the prior notice submission includes: (1) The submitter and transmitter (if different from the submitter); (2) entry type and CBP identifier; (3) the article of food, including complete FDA product code; (4) the manufacturer, for an article of food no longer in its natural state; (5) the grower, if known, for an article of food that is in its natural state; (6) the FDA Country of Production; (7) the name of any country that has refused entry of the article of food; (8) the shipper, except for food imported by international mail; (9) the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; (10) the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; (11) the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; (12) the carrier and mode of transportation, except for food imported by international mail; and (13) planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 reflects FDA's estimate of the reduced burden for prior

notice submitted through ABI/ACS in column 6, entitled ''Average Burden per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to FDA if information changes after the Agency has confirmed a prior notice submission for review (*e.g.,* if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l) of the FD&C Act, §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting FDA's review and the information required in a request for review. In the event that the Agency places an article of food under hold under § 801(l) of the FD&C Act, § 1.285(i) sets forth the procedure for, and the information to be included in, a post-hold submission.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section No.	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Prior Notice Submissions						
Prior Notice Submitted Through ABI/ACS						
1.280–1.281	None	1,700	7647	12,999,900	0.167 (10 minutes)	[2] 2,170,983
Prior Notice Submitted Through PNSI						
1.280–1.281	[3] 3540	27,000	70	1,890,000	0.384 (23 minutes)	725,760
New Prior Notice Submissions Subtotal.						2,896,743
Prior Notice Cancellations						
Prior Notice Cancelled Through ABI/ACS						
1.282	3540	7,040	1	7,040	0.25 (15 minutes)	1760
Prior Notice Cancelled Through PNSI						
1.282, 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 minutes)	8,802
Prior Notice Cancellations Subtotal.						10,562
Prior Notice Requests for Review and Post-Hold Submissions						
1.283(d), 1.285(j),	None	1	1	1	8	8
1.285(i)	None	263	1	263	1	263
Prior Notice Requests for Review and Post-Hold Submissions Subtotal.						271
Total						2,907,576

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

[2] To avoid double-counting, an estimated 396,416 burden hours already accounted for in the Importer's Entry Notice information collection approved under OMB control number 0910–0046 are not included in this total.

[3] The term ''Form FDA 3540'' refers to the electronic submission system known as PNSI, which is available at *http://www.access.fda.gov.*

This estimate is based on FDA's experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years.

FDA received 10,450,824 prior notices through ABI/ACS during 2014; 11,282,015 during 2015; and 12,153,880 during 2016. Based on this experience, the Agency estimates that approximately 1,700 users of ABI/ACS will submit an average of 7,647 prior notices annually, for a total of 12,999,900 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hour, per notice, for a total burden of 2,170,983 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA importer's entry notice (OMB control number 0910–0046), as previously discussed.

FDA received 1,529,110 prior notices through PNSI during 2014; 1,633,567 during 2015; and 1,768,790 during 2016. Based on this experience, the Agency estimates that approximately 27,000 registered users of PNSI will submit an average of 70 prior notices annually, for a total of 1,890,000 prior notices received annually. FDA estimates the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hour, per notice, for a total burden of 725,760 hours.

FDA received 7,265 cancellations of prior notices through ABI/ACS during 2014; 7,910 during 2015; and 5,948 during 2016. Based on this experience, the Agency estimates that approximately 7,040 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 7,040 cancellations received annually through ABI/ACS. FDA estimates the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 1,760 hours.

FDA received 36,324 cancellations of prior notices through PNSI during 2014; 39,553 during 2015; and 29,743 during 2016. Based on this experience, the Agency estimates that approximately 35,208 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 35,208 cancellations received annually. FDA estimates the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 8,802 hours.

FDA has not received any requests for review under § 1.283(d) or § 1.285(j) in the last 3 years; therefore, the Agency estimates that one or fewer requests for review will be submitted annually. FDA estimates that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, the Agency has estimated a total reporting burden of 8 hours.

FDA received 235 post-hold submissions under § 1.285(i) during 2014; 218 during 2015; and 337 during 2016. Based on this experience, the Agency estimates that 263 post-hold submissions under § 1.285(i) will be submitted annually. FDA estimates that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, the Agency estimates a total reporting burden of 263 hours.

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–32030 Filed 1–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The National Health Service Corps Loan Repayment Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than February 6, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The National Health Service Corps Loan Repayment Program.

OMB No. 0915–0127 Revision.

Abstract: The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. Under this program, the Department of Health and Human Services agrees to repay the qualifying educational loans of selected primary care health professionals. In return, the health professionals agree to serve for a specified period of time in an NHSC-approved site located in a federally-designated HPSA approved by the Secretary for LRP participants. The forms used by the LRP include the following: The NHSC LRP Application, the Authorization for Disclosure of Loan Information form, the Privacy Act Release Authorization form, and if applicable, the Verification of Disadvantaged Background form and the Private Practice Option form. The first four of the aforementioned NHSC LRP forms collect information that is needed for selecting participants and repaying qualifying educational loans. The last referenced form, the Private Practice Option Form, is needed to collect information for all participants who have applied for that service option.

NHSC-approved sites are health care facilities that provide comprehensive outpatient, ambulatory, primary health care services to populations residing in HPSAs. Related in-patient services may be provided by NHSC-approved Critical Access Hospitals (CAHs). To become an NHSC-approved site, new sites must submit a Site Application for review and approval. Existing NHSC-approved sites are required to complete a Site Recertification Application to maintain their NHSC-approved status. Both the NHSC Site Application and Site Recertification Application request information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing these applications may be obtained through the appropriate State Primary Care Offices and HRSA's NHSC program office. The information collected on the applications is used for determining the eligibility of sites for the assignment of NHSC health professionals and to verify the need for NHSC clinicians. NHSC service site approval is valid for 3 years. Sites wishing to remain eligible for the assignment of NHSC providers must submit a Site Recertification Application every 3 years.

The proposed ICR is a revision to OMB control number 0915–0127 (NHSC LRP) by combining previously approved OMB number 0915–0230 (NHSC Site Application and Site Recertification Application forms) and adding a new form to the ICR called the NHSC Comprehensive Behavioral Health Services Checklist.

Need and Proposed Use of the Information: The need and purpose of this information collection is to obtain information that is used to assess an LRP applicant's eligibility and qualifications for the LRP and obtain information for NHSC site applicants. Clinicians interested in participating in the NHSC LRP must submit an application to the NHSC to participate in the program, and health care facilities