314.71 for NDAs and approximately 2,075 responses under § 314.97 for ANDAs. The number of annual frequencies per response is estimated to decrease. FDA estimates that approximately the same number of respondents will submit responses under §§ 314.70, 314.71, and 314.97 and each response will take approximately the same amount of time to prepare as in the information collection currently approved under OMB Control Number 0910–0001.

As set forth in the following table, the estimated annual reporting burden for this information collection is 286,000 hours. In the future, it is estimated that the Agency would reduce the currently approved burden (OMB Control Number 0910–0001) for §§ 314.70 and 314.71 for NDAs and § 314.97 for ANDAs by reducing the number of supplements for those postapproval CMC changes that can be documented in annual reports as recommended in the ''Guidance for Industry on CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports.''

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Supplements and Annual Reports for NDAs.	281 (same as currently approved).	2.85	800	150 (same as currently approved).	120,000
Supplements and Annual Reports for ANDAs.	215 (same as currently approved).	9.65	2,075	80 (same as currently approved).	166,000
Total Hours					286,000

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25973 Filed 10–31–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0179]

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 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 (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 our regulations requiring that the Agency receive 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 December 31, 2013.

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, 301–796–3793, *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, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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 we receive 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 our 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 our review after we have 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.'' In the **Federal Register** of May 5, 2011 (76 FR 25542), we issued an interim final rule (IFR) entitled ''Information Required in Prior Notice of Imported Food'' (2011 IFR) that implemented section 304 of FSMA and requested public comments. OMB approved the collection of information requirements of the 2011 IFR under OMB control number 0910–0683. On May 30, 2013 (78 FR 32359), we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. In this request for extension of OMB approval under the PRA, we are combining the burden hours associated with OMB control number 0910–0683 (collection entitled ''Information Required in Prior Notice of Imported Food'') with the burden hours approved under OMB control number 0910–0520 (collection entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002''). If approved, we will discontinue the information collection in OMB control number 0910–0683, having incorporated the burden into OMB control number 0910–0520.

Advance notice of imported food allows us, 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, we may better identify imported food shipments that may pose safety and security risks to U.S. consumers. This additional knowledge can further help us 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.

Our 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 we collect in the prior notice submission includes: The submitter and transmitter (if different from the submitter); entry type and CBP identifier; the article of food, including complete FDA product code; the manufacturer, for an article of food no longer in its natural state; the grower, if known, for an article of food that is in its natural state; the FDA Country of Production; the name of any country that has refused entry of the article of food; the shipper, except for food imported by international mail; 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; the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; the carrier and mode of transportation, except for food imported by international mail; and 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 our 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 of this document reflects our 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 us if information changes after we have 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 we have confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (a)(1)(iii)). In the event that we refuse admission to an article of food under section 801(m)(1) of the FD&C Act or we place it under hold under section 801(l), §§ 1.283(d) and 1.285(j) set forth the procedure for requesting our review and the information required in a request for review. In the event that we place an article of food under hold under section 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.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions						
Prior Notice submitted through ABI/ACS:						
1.280, 1.281	([4])	15,000	608	9,120,000	0.167	[2] 1,523,040
Prior Notice submitted through PNSI:						
1.280, 1.281	[3] 3540	26,667	58	1,546,686	0.384	593,927
New Prior Notice Submissions Subtotal	.....	.....	.....	.....	.....	2,116,967

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Cancellations						
Prior Notice cancelled through ABI/ACS:						
1.282	3540	4,098	1	4,098	0.25	1,025
Prior Notice cancelled through PNSI:						
1.282, 1.283(a)(5)	3540	33,096	1	33,096	0.25	8,274
Prior Notice Cancellations Subtotal	.....	.....	.....	.....	.....	9,299
Prior Notice Requests for Review and Post-hold Submissions:						
1.283(d), 1.285(j)	([4])	1	1	1	8	8
1.285(i)	([4])	1	1	1	1	1
Prior Notice Requests for Review and Post-hold Submissions Subtotal	.....	.....	.....	.....	.....	9
Total Hours Annually	.....	.....	.....	.....	.....	2,126,275

[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 No. 0910–0046 are not included in this total.
[3] The term "Form FDA 3540" refers to the electronic submission system known as the Prior Notice System Interface (PNSI), which is available at *http://www.access.fda.gov*.
[4] None.

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

As discussed, on May 30, 2013, we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. We estimate that it would take on average about one additional minute (0.016 hours) per entry for each respondent to submit prior notice with this additional piece of information. Accordingly, we have increased our estimate of the hours per response for prior notices received through ABI/ACS from 9 minutes, or 0.15 hours, per notice, to 10 minutes, or 0.167 hours, per notice. We have also increased our estimate of the hours per response for prior notices received through PNSI from 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice, to 23 minutes, or 0.384 hours, per notice.

We received 8,570,504 prior notices through ABI/ACS during 2010; 9,054,187 during 2011; and 9,716,147 during 2012. Based on this experience, we estimate that approximately 15,000 users of ABI/ACS will submit an average of 608 prior notices annually, for a total of 9,120,000 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 hours, per notice, for a total burden of 1,523,040 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for our importer's entry notice (OMB Control No. 0910–0683), as previously discussed in this document.

We received 1,566,029 prior notices through PNSI during 2010; 1,498,609 during 2011; and 1,524,901 during 2012. Based on this experience, we estimate that approximately 26,667 registered users of PNSI will submit an average of 58 prior notices annually, for a total of 1,546,686 prior notices received annually. We estimate the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hours, per notice, for a total burden of 593,927 hours.

We received 4,488 cancellations of prior notices through ABI/ACS during 2010; 3,993 during 2011; and 3,812 during 2012. Based on this experience, we estimate that approximately 4,098 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 4,098 cancellations received annually through ABI/ACS. We estimate the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 1,024.5 hours, rounded to 1,025 hours.

We received 33,353 cancellations of prior notices through PNSI during 2010; 33,343 during 2011; and 32,592 during 2012. Based on this experience, we estimate that approximately 33,096 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 33,096 cancellations received annually. We estimate the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 8,274 hours.

We have not received any requests for review under § 1.283(d) or § 1.285(j) in the last 3 years (2010, 2011, and 2012); therefore, we estimate that one or fewer requests for review will be submitted annually. We estimate that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we have estimated a total reporting burden of 8 hours.

We have not received any post-hold submissions under § 1.285(i) in the last 3 years (2010, 2011, and 2012); therefore, we estimate that one or fewer post-hold submissions will be submitted annually. We estimate that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, we have estimated a total reporting burden of 1 hour.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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