Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
OMB Control No. 0910-0520
SUPPORTING STATEMENT, Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

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) (21 CFR 1.285(i)) sets forth the procedure for post-hold submissions.

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, 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.

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.

This is a revision request in which the agency seeks to extend the approvals listed below and to incorporate the burden from OMB Control No. 0910-0683, "Information Required in Prior Notice of Imported Food."

We request the extension of OMB approval for the following collection of information requirements and form:

21 CFR 1.280 - 1.281 -- Reporting

Requires submission of a prior notice to FDA, sets forth the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required.

21 CFR 1.282, 1.283(a)(5) -- Reporting

Requests cancellation of a prior notice in the event that certain information changes after confirmation of a prior notice has been received by FDA.

21 CFR 1.283(d), 1.285(i), and 1.285(j)-- Reporting

Establishes procedures for submitting a request for FDA review after the agency has refused admission of an article of food under 801(m)(1) of the act.

21 CFR 1.285(j)-- Reporting

Establishes procedures for submitting a request for FDA review after the agency has placed an article of food under hold under 801(l) of the act.

Form FDA 3540

The term "Form FDA 3540" refers to the electronic system known as the FDA Prior Notice (PN) System Interface, which is available at http://www.access.fda.gov.

2. Purpose and Use of the Information Collection

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).

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 1.282(a)(1)(iii)). In the event that we refuse admission to an article of food under section 801(m)(1) or we place it under hold under section 801(l) of the (FD&C Act), §§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.

FDA uses the information, with the support of CBP, to target import inspections more effectively and to help protect the nation's food supply against terrorist acts and other public health emergencies.

Description of Respondents: Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection include importers, owners, ultimate consignees, shippers, and carriers with knowledge of the required information about food, including food for animals, that is imported or offered for import into the United States. Respondents include, unless otherwise exempt, individuals and households, the private sector (including for-profit businesses, not-for-profit institutions and farms), state local or tribal governments, as well as the Federal government.

3. Use of Improved Information Technology and Burden Reduction

As noted above, FDA's regulations require that prior notice of imported food be submitted electronically either through ABI/ACS or the FDA PN System Interface. Thus, FDA estimates that one hundred percent (100%) of the respondents will use electronic means to submit the required information.

4. Efforts to Identify Duplication and Use of Similar Information

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 the column labeled "Hours per Response."

The ABI/ACS information cannot substitute for the submission of prior notice because it does not meet the requirements of the Bioterrorism Act, such as providing FDA with certain specified information before the food arrives in the United States. Entry may be made up to 15 days after a food arrives in the U.S. and does not contain all of the information required in a prior notice, such as the country from which the article is shipped. The information in a prior notice is necessary for FDA to determine whether it should examine the food at the U.S. port of arrival.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately ninety percent (90%) of the respondents are small businesses.

The reporting requirements of this regulation are those mandated by the Bioterrorism Act and there is no statutory exception for small businesses in that act. However, FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/. In addition, FDA's Prior Notice Center can answer questions about Prior Notice policies, procedures and interpretations, and will attempt to assist small businesses to comply with prior notice. The Prior Notice Center staff is available is available 24 hours a day, 365 days a year.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Respondents will submit the required information on an occasional basis, as required by section 801(m) of the act. If the collection is not conducted or is conducted less frequently, the importers, owners, ultimate consignees, shippers, and/or carriers will not be in compliance with section 801(m) of the act. Without prior notice of every imported shipment it would not be possible to protect the nation's food supply against terrorist acts and other public health emergencies.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of November 1, 2013 (78 FR 65670), FDA published a 60-day notice requesting public comment on the collection of information. The agency received several comment letters that were not responsive to the comment request on the collection of information and are therefore not discussed here.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The regulation does not specify confidentiality. However, confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). The information also is safeguarded by Section 301(j) of the act (21 U.S.C. 331(j).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1- Estimated Annual Reporting Burden[1]

21 CFR Section No.	FDA Form No.	No. of Respondents	No. 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	None	15,000	608	9,120,000	0.167	1,523,040[2]
Prior Notice submitted through PNSI						
1.280-1.281	FDA 3540[3]	26,667	58	1,546,686	0.384	593,927
					New Prior Notice Submissions Subtotal	2,116,967
Prior Notice Cancellations						
Prior Notice cancelled through ABI/ACS						
1.282	FDA 3540	4,098	1	4,098	0.25	1,025
Prior Notice cancelled through PNSI						
1.282, 1.283(a)(5)	FDA 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),	None	1	1	1	8	8
1.285(i)	None	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.

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, 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.

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $127,278,821.50. FDA estimates that the prior notice process will involve an employee making an average wage similar that of a Federal government employee at the GS-11/Step-1 rate for the Washington-Baltimore locality pay area for the year 2013, which is $29.93 per hour. To account for overhead, this cost is increased by 100 percent, which is $59.86 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $127,278,821.50 (1,859,474 2,126,275 hours x $59.86 per hour).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA's costs to develop the PN System Interface include design, development, and implementation, software and security, and a network interface. FDA estimates these costs to be $12.5 million.

15. Explanation for Program Changes or Adjustments

This ICR adds a previously approved collection. Under OMB Control No. 0910-0683 FDA was given approval for an information collection request that allowed for additional reporting elements under its regulations regarding prior notice of imported food – to report any country for which an article of food has been refused entry. The agency wishes to consolidate that collection into this one to eliminate redundancy, and has revised its burden estimate to accordingly. Overall, the agency revised its estimates for four of the six individual information collections resulting in an overall increase of **665,380** annual responses and **266,801** burden hours. A breakdown of these adjustments is as follows:

Individual Information Collection	*Annual Responses*	*Hourly Burden*
IC #1: Reporting through ABI/ACS	735,000	265,290
IC #2: Reporting through PN System	(22814)	13212
IC #3: Cancellation through ABI/ACS	(15402)	(3850)
IC #4: Cancellation through PN System	(31404)	(7851)
Overall increase	**665,380**	**266,801**

The first IC was increased as agency records show more respondents using the automated broker interface (ABI/ACS) electronic reporting system; the burden hours were also increased to reflect the higher number of users as well as to reflect the reporting element previously captured under 0910-0683. Conversely, we reduced our estimate in IC#2 as fewer respondents are using the prior notice system interface (PNSI). At the same time, we increased the hourly burden for IC#2 to reflect the added reporting element previously captured under 0910-0683. For ICs 3 and 4, the agency decreased its estimate as fewer cancellation reports were received utilizing either reporting mechanism. Our estimates for IC #s 5 and 6 remain unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA has no reason for not displaying the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.