FOOD AND DRUG ADMINISTRATION
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

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection helps support the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which added section 801(m) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), requiring that the Food and Drug Administration (FDA or we) receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Regulations found in 21 CFR Part 1; Subpart I govern "*Prior Notice of Imported Food*." Specifically, sections 1.278 to 1.282 (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*."

Accordingly, we request OMB approval of the information collection provisions found in 21 CFR Part 1; Subpart I and discussed below.

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 name of 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

Because much of the information being collected under this request is similar to information that may be collected under OMB Control No. 0910–0046 (*Importer's Entry Notice*), we have confined our burden estimate to only those elements described in section 801 of the FFDCA exclusively related to prior notice of imported foods (versus FDA-regulated products more generally) and discussed in this supporting statement. Information collection burden that may be associated with other regulations governing the import of FDA-regulated products is approved under OMB Control No. 0910-0046 and discussed in the agency's supporting statement.

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 for 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), FDA published a 60 day notice for public comment in the Federal Register of January 5, 2017 (82 FR 1349). No comments were received.

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:						
Through ABI/ACS						
1.280-1.281	N/A	1,700	7,647	12,999,900	0.167 (10 mins.)	2,170,983
Through PNSI						
1.280-1.281	3540	27,000	70	1,890,000	0.384 (23 mins.)	725,760
					Subtotal:	2,896,743
CANCELLATIONS:						
Through ABI/ACS						
1.282	3540	7,040	1	7,040	0.25 (15 mins.)	1,760
Through PNSI						
1.282, 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 mins.)	8,802
					Subtotal:	10,562
REQUESTS FOR REVIEW AND POST-HOLD SUBMISSIONS:						
1.283(d), 1.285(j),	N/A	1	1	1	8	8
1.285(i)	N/A	263	1	263	1	263
					Subtotal:	271
TOTAL:				**14,932,412**		**2,907,576**

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

Table 1 reflects the annual estimated reporting burden associated with the information collection. During calendar years 2014, 2015, and 2016 we received 10,450,824, 11,282,015, and 12,153,880 prior notice submissions respectively from approximately 1,700 users of ABI/ACS. During the next three years, we estimate each respondent needed approximately 10 minutes per submission for a total of 12,999,900 annual submissions and 2,170,983 annual hours of burden. Similarly, during the same period (2014-2016) we received 1,529,110, 1,633,567, 1,768,790 submissions through PNSI

where we counted 27,000 users submitting an average of 70 notices annually, requiring approximately 23 minutes per submission. Cumulatively this totals 1,890,000 annual responses and 725,760 annual hours of burden.

Regarding cancellations of prior notices, during 2014, 2015, and 2016 we received 7,265, 7,910, and 5,948 submissions respectively through ABI/ACS, where we counted 7,040 respondents averaging 1 cancellation annually and requiring 15 minutes to do so. Cumulatively this totals 7,040 annual submissions and 1,760 annual hours of burden. Similarly, during the same period (2014-2016) we received 36,324, 39,553, and 29,743 cancellations through PNSI where we counted 35,208 registered users submitting an average of 1 cancellation annually and requiring 15 minutes to do so. Cumulatively this totals 35,208 annual responses and 8,802 annual hours of burden.

While we have not received any submissions under § 1.283(d) or § 1.285(j) in the last 3 years; we estimate at least one response for purposes of retaining collection authority under this provision. Estimating it will take approximately 8 hours to prepare a submission, this totals one annual response and 8 hours of burden.

Finally, during calendar years 2014, 2015, and 2016 we received 235, 218, and 337 post-hold submissions respectively. For an average of 263 submissions annually we estimate it will take respondents 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total of 263 annual burden hours.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized cost burden to respondents for this collection of information is $127,278,821.50. FDA estimates that the prior notice process will involve an employee making an average wage similar to that of a Federal government employee at the GS-11/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017 ($31.87/hour). To account for overhead, this cost is increased by 100 percent, which is $63.74 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $185,328,894 (2,907,576 hours x $63.74 per hour).

Table 2. Annual Cost Burden Estimate

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Prior Notice submissions, cancellations, and review and post hold submissions	2,907,576	$63.74	$185,328,894

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 incurs costs to operate and maintain the PN System Interface and estimates those costs to be approximately $1 million annually.

15. Explanation for Program Changes or Adjustments

This information collection includes adjustments. Based on our review, the collection reflects a continued increase in submissions. As a result we have increased our annual estimate by 4,228,530 responses and 781,301 burden hours. Burden associated with the individual ICs and our corresponding calculations are discussed more fully under Q12 of this supporting statement.

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.