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

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 (the act) (21 U.S.C. 381(m)) (Attachment A), which requires that FDA 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 FDA's 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 FDA review after an article of food has been refused admission under section 801(m)(1) of the act or placed under hold under section 801(l) of the act; and § 1.285(i) (21 CFR 1.285(i)) sets forth the procedure for post-hold submissions (Attachment B). Advance notice of imported food allows FDA, with the support of the Bureau of 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.

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

FDA's 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 (PN) System Interface Form (FDA 3540). Information collected by FDA 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 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 if information changes after FDA 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 FDA has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to 1.282(a)(1)(iii)). In the event that an article of food has been refused admission under section 801(m)(1) or placed under hold under section 801(l) of the act, §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA review and the information required to be included in a request for review. In the event that an article of food has been placed under hold under section 801(l) of the 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: Respondents to this collection of information 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 FDA's importer's entry notice, which has been approved under OMB control number 0910-0046. The information in FDA's 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 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.
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

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 March 16, 2010 (75 FR 12549), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. FDA received one letter, containing multiple comments, in response to the notice. These comments were outside the scope of the four collection of information topics on which the notice solicits comments.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift 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).

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

21 CFR Section No.	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
Prior Notice Submissions						
Prior Notice submitted through ABI/ACS						
1.280-1.281	None	6,500	1,290	8,385,000	0.15	1,257,750[2]
Prior Notice submitted through PN System Interface						
1.280-1.281	FDA 3540[3]	21,500	73	1,569,500	0.37	580,715
					New Prior Notice Submissions Subtotal	1,838,465
Prior Notice Cancellations						
Prior Notice cancelled through ABI/ACS						
1.282	FDA 3540	6,500	3	19,500	0.25	4,875

Prior Notice cancelled through PN System Interface						
1.282, 1.283(a) (5)	FDA 3540	21,500	3	64,500	0.25	16,125
					Prior Notice Cancellations Subtotal	21,000
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	1,859,474

[1]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.
[2]The term "Form FDA 3540" refers to the electronic system known as the FDA PN System Interface, 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.

In the Federal Register of November 7, 2008 (73 FR 66294), FDA and CBP issued the prior notice final rule, which finalized the prior notice interim final rule (IFR) (October 10, 2003, 68 FR 58974). From the IFR to the final rule, FDA removed a few of the required prior notice data elements. Specifically, submitters no longer need to include the fax number of the submitter and transmitter, the anticipated border crossing, the country of the carrier, or the 6–digit HTS code in their prior notices. Other changes include the addition of the registration number of the transshipper for articles of food for transshipment, storage and export, or manipulation and export; flexibility in submitting the registration number and the city and country of the manufacturer and shipper instead of full addresses of these entities; and the option of submitting the tracking number for articles of food arriving by express consignment instead of anticipated arrival information when the prior notice is submitted through the PN System Interface (73 FR 66293, at 66402). In the final rule, FDA estimated that the changes in the filing requirements would not affect the time needed to file prior notice (73 FR 66293, at 66402). Based on its experience during the last two years, FDA now estimates that the hours per response were reduced by the changes. Accordingly, FDA has reduced its estimate of the hours per response for prior notices received through ABI/ACS from 10 minutes, or 0.167 hours, per notice, to 9 minutes, or 0.15 hours, per notice. FDA has also reduced its estimate of the hours per response for prior notices received through the PN System Interface from 23 minutes, or 0.384 hours, per notice, to 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice.

FDA received 8,144,419 prior notices through ABI/ACS during 2007; 8,266,200 during 2008; and 5,221,549 as of August 26, 2009. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 1,290 prior notices annually, for a total of 8,385,000 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/ACS to be 9 minutes, or 0.15 hours, per notice, for a total burden of 1,257,750 hours. This estimate takes into consideration the burden hours already counted

in the information collection approval for FDA's importer's entry notice, as previously discussed in this document.

FDA received 1,744,287 prior notices through the PN System Interface during 2007; 1,662,033 during 2008; and 989,708 as of August 26, 2009. Based on this experience, FDA estimates that approximately 21,500 registered users of the PN System Interface will submit an average of 73 prior notices annually, for a total of 1,569,500 prior notices received annually through the PN System Interface. FDA estimates the reporting burden for a prior notice submitted through the PN System Interface to be 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice, for a total burden of 580,715 hours.

FDA received 16,215 cancellations of prior notices through ABI/ACS during 2007; 16,673 during 2008; and 16,045 as of August 26, 2009. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 2.64 (rounded to 3) cancellations annually, for a total of 19,500 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 hours, per cancellation, for a total burden of 4,875 hours.

FDA received 58,345 cancellations of prior notices through the PN System Interface during 2007; 63,779 during 2008; and 55,019 as of August 26, 2009. Based on this experience, FDA estimates that approximately 21,500 registered users of the PN System Interface will submit an average of 3.24 (rounded to 3) cancellations annually, for a total of 64,500 cancellations received annually through the PN System Interface. FDA estimates the reporting burden for a cancellation submitted through the PN System Interface to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 16,125 hours.

FDA has not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (2007 through August 26, 2009); 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, FDA has estimated a total reporting burden of 8 hours.

FDA has not received any post-hold submissions under § 1.285(i) in the last 3 years (2007 through August 26, 2009); therefore, the agency estimates that one or fewer post-hold submissions 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, FDA has 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 $111,308,113.64. 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 2010, 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 $111,308,113.64 (1,859,474 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 that these costs will total $12.5 million.

15. Explanation for Program Changes or Adjustments

The burden hours increased from 1,749,913 to 1,859,474 hours, a difference of 109,561 hours. This is due to two factors. There was a large increase in the total number of prior notices submitted, an increase of 1,992,624 responses. The total number of responses is now 10,038,502. The second factor is a slight decrease in the estimated time required for each respondent to complete these forms. Based on experience in the field, FDA now estimates some required responses have a slightly decreased burden. The net effect of these changes is a burden increase of 109,561 hours.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.