

United States 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

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). 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 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 (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.

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 specific 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 information enables us to make better informed decisions in managing the potential risks of imported food shipments into the United States. Section 304 of the FSMA 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.” To facilitate submission of information to FDA, we developed Form FDA 3540, or the FDA Prior Notice System Interface (PNSI), for use with CBP systems.

We therefore request extension of OMB approval of the information collection provisions found in 21 CFR part 1, Subpart I and Form FDA 3540 as discussed in this supporting statement.

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 Environment (ABI/ACE) (§1.280(a) (1)) or FDA’s PNSI (§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: (1) the name of 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 (Importer's Entry Notice). The information in an importer's entry notice is collected electronically via CBP's ABI/ACE 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/ACE 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 (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 FDA's 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 use 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/ACE or PNSI. Thus, we estimate 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

We are unaware of duplicative information collections. 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 (Importer's Entry Notice). The information in an importer's entry notice is collected electronically via CBP's ABI/ACE 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/ACE in column 6 entitled "Average Burden per Response."

5. Impact on Small Businesses or Other Small Entities

Although we estimate that approximately ninety percent (90%) of the respondents are small businesses, we believe the information collection poses no undue burden on small entities. The reporting requirements are those mandated by the Bioterrorism Act with no statutory exception for small businesses. However, we aid small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via our Small Business Assistance webpage at <https://www.fda.gov/industry/small-business-assistance>. With regard to Prior Notice specifically, we have established the following resources:

System Help Desk

800-216-7331 

240-247-8804  INTL

Contact for questions regarding PNSI account creation, management, password reset, and technical computer questions. (Mon–Fri 7:30 am - 11:00 pm EST)

Division of Food Defense Targeting (formerly Prior Notice Center)

866-521-2297 

571-468-1488  INTL

571-468-1936  Fax

prior.notice@fda.hhs.gov

Contact for questions regarding prior notice policies, procedures, and interpretations. (24/7)

Division of Import Operations & Policy

301-796-0356 

Contact for import questions not related to prior notice.

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 FD&C Act. If the collection is conducted less frequently, the respondents will not be in compliance with statutory and regulatory requirements. Without advance notice of imported food, FDA along with CBP, would be unable

to target import inspections effectively and hamper their ability 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), we published a 60-day notice for public comment in the *Federal Register* of February 27, 2023 (88 FR 12366). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3540 (Prior Notice System Interface/PNSI) is user credentials (username and password), name, email address, telephone number, and fax telephone number. FDA determined that, although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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 Cost

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section No.	FDA Form	No. of Respondents	No. of Responses	Total Annual	Average Burden per	Total Hours
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	No.		per Respondent	Responses	Response	
PRIOR NOTICE SUBMISSIONS:						
<i>Through ABI/ACE</i>						
1.280-1.281	N/A	1,900	7,895	15,000,500	0.167 (10 mins.)	² 2,505,084
<i>Through PNSI</i>						
1.280-1.281	³ 3540	13,000	231	3,003,000	0.384 (23 mins.)	1,153,152
Subtotal:						3,658,236
CANCELLATIONS:						
<i>Through ABI/ACE</i>						
1.282	N/A	25,000	1	25,000	0.25 (15 mins.)	6,250
<i>Through PNSI</i>						
1.282, 1.283(a)(5)	3540	50,000	1	50,000	0.25 (15 mins.)	12,500
Subtotal:						18,750
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	500	1	500	1	500
Subtotal:						508
TOTAL:				18,079,001		3,677,494

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 the total.

³ The term "Form FDA 3540" refers to the electronic submission system known as PNSI, which is available at <https://www.access.fda.gov/>.

The estimates in Table 1 are based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years. During the next three years, we estimate respondents submitting via ABI/ACE will need approximately 10 minutes per submission for a total of 15,000,500 annual submissions and 2,505,083.5 rounded up to 2,505,084 annual hours of burden. Similarly, we estimate respondents submitting via PNSI will need approximately 23 minutes per submission for a total of 3,003,000 annual submissions and 1,153,152 annual hours of burden. Cumulatively, this totals 18,003,500 annual responses and 3,658,236 annual hours of burden.

Regarding cancellations of prior notices, we estimate 25,000 respondents using ABI/ACE average 1 cancellation annually and requires 15 minutes to do so for a total of 6,250 annual hours of burden. Similarly, we estimate 50,000 respondents using PNSI average 1 cancellation annually and requires 15 minutes to do so for a total of 12,500 annual hours of burden. Cumulatively, cancellation of prior notices totals 75,000 annual responses and 18,750 annual hours of burden.

We estimate that we will receive one submission annually under §§ 1.283(d) or 1.285(j) over the next 3 years. It takes approximately 8 hours to prepare a submission, which results in 8 hours of burden.

Finally, for an average of 500 post-hold submissions annually, we estimate it takes

respondents 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total of 500 annual burden hours.

12b. Annualized Cost Burden Estimate

We estimate the annualized cost burden to respondents for this collection of information is \$276,988,848. We estimate 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 2023 (\$37.66/hour). To account for overhead, this cost is increased by 100 percent, which is \$75.32 per hour. Thus, the annual wage cost imposed by this collection of information is approximately \$276,988,848 (3,677,494 hours x \$75.32 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	3,677,494	\$75.32	\$276,988,848

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

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

14. Annualized Cost to the Federal Government

We estimate an annual cost of \$1,000,000 to operate and maintain the Prior Notice System Interface (PNSI).

15. Explanation for Program Changes or Adjustments

We are adjusting our burden estimate for this information collection by increasing the number of responses and total burden. The number of responses has increased by 3,146,589 responses (from 14,932,412 to 18,079,001). The total burden has increased by 769,918 hours (from 2,907,576 to 3,677,494). We attribute the adjustment to an increase in the number of responses.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published or tabulated.

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

Displaying the OMB approval date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.