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 implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), requires 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 procedures for requesting FDA review if admission of an article of food under section 801(m)(1) of the FD&C Act has been refused or placed on 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.

To facilitate submission of information to FDA, we developed Form FDA 3540, or the *Prior Notice System Interface* (PNSI), for use with CBP systems. 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 extension of OMB approval of the information collection provisions found in 21 CFR part 1; Subpart I and Form FDA 3540.

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)) through 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 collected via 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.

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 regulations require that prior notice of imported food be submitted electronically either through ABI/ACE or the FDA 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 collection. Although similar information collection is accounted for under OMB control no. 0910-0046 in conjunction with FDA's import program

generally, here we are exclusively accounting for those elements described in section 801 of the FD&C Act related to prior notice of imported foods, as discussed in this supporting statement.

5. Impact on Small Businesses or Other Small Entities

Although we estimate that ninety percent (90%) of respondents are small businesses, we do not believe the information collection poses undue burden on small entities. At the same time, we assist small businesses through our Regional Small Business Representatives. We also provide a Small Business Guide on our website 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 is consistent with statutory and regulatory requirements that mandate public health protection measures be employed regarding the United States' food supply.

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 6, 2020 (85 FR 6955). Because the one comment received was not responsive to the information collection topics solicited, it was not addressed.

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 handling. While FDA has minimized the PII to be collected to protect the privacy of the individuals, the collection of information does not specifically pledge 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 our regulations (21 CFR part 20). The information collected is also protected by Section 301(j) of the Act (21 U.S.C. 331(j).

Privacy Act

This ICR collects personally identifiable information or information of a personal nature. The PII collected is for business contact purposes only and includes business name, business address, business telephone numbers. The business contact information is maintained and stored at the vendor facility.

FDA further determined that although PII is collected and stored at the vendor facility 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 routinely retrieve records from the information collected.

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

Our estimate of the burden for this collection of information is 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/ACE						
1.280-1.281	N/A	1,900	7,895	15,000,500	0.167 (10 mins.)	2,505,084
Through PNSI						
1.280-1.281	3540	13,000	231	3,003,000	0.384 (23 mins.)	1,153,152
					Subtotal:	3,658,236
CANCELLATIONS:						
Through ABI/ACE						

1.282	3540	25,000	1	25,000	0.25 (15 mins.)	6,250
Through PNSI						
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.

Table 1 reflects the annual estimated reporting burden associated with the information collection. During the next three years, we estimate each respondent 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 13,000 users submitting an average of 231 notices annually, requiring approximately 23 minutes per submission. Cumulatively, this totals 3,003,000 annual responses and 1,153,152 annual hours of burden.

Regarding cancellations of prior notices, we estimate 25,000 respondents averaging 1 cancellation annually and requiring 15 minutes to do so. Cumulatively this totals 25,000 annual submissions and 6,250 annual hours of burden. Similarly, we estimate 50,000 registered users submitting an average of 1 cancellation annually and requiring 15 minutes to do so. Cumulatively this totals 50,000 annual responses and 12,500 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, for an average of 500 post-hold 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 500 annual burden hours.

12b. Annualized Cost Burden Estimate

We estimate the annualized cost burden to respondents for this collection of information is $253,820,635.88. 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 2020 ($34.51/hour). To account for overhead, this cost is increased by 100 percent, which is $69.02 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $253,820,635.88 (3,677,494 hours x $69.02 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	$69.02	$253,820,635.88

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

Based on our evaluation of the information collection, we have made no adjustments.

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.