

UNITED STATES FOOD AND DRUG ADMINISTRATION

Prior Notice: Adding Requirement to Submit Mail Tracking Number for Articles of Food Arriving by International Mail and Timeframe for Post-refusal and Post-hold Submissions

RIN 0910-AI75

OMB Control No. 0910-0923

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) rulemaking intended to help implement 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) issue regulations requiring the submission of prior notice for food, including food for animals, that is imported or offered for import into the United States. FDA's regulations requiring such notice appear in 21 CFR Part 1; Subpart I "*Prior Notice of Imported Food.*"

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.

We are proposing to amend the regulation to include a requirement that the name of the mail service and a mail tracking number be submitted for articles of food arriving by international mail, in the prior notice of the article of food to FDA. This information will assist FDA's abilities to work with the U.S. Customs and Border Protection (CBP) and the United States Postal Services (USPS) to locate, hold, and inspect mail shipments of articles of food when there is information that the article could pose a threat to the U.S. food supply and will assist FDA in better utilizing its resources efficiently and effectively in ensuring the safety of food articles arriving by international mail.

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 through the FDA Prior Notice System Interface (PNSI) (§1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at <http://www.access.fda.gov/>.

For food articles arriving by international mail, the information that must be submitted includes the name of the submitter and transmitter (if different from the submitter); entry type; the identify of 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; the country from which the article of food is shipped (i.e. mailed); the anticipated date of mailing; and the name and address of the U.S. recipient.

If the food is not arriving by international mail (e.g. it is arriving via private delivery service), the information must include anticipated arrival information, such as anticipated port, date and time of arrival. The rule requires the submission of anticipated arrival information for such shipments to provide FDA with information necessary for planning examinations and communicating with CBP for enforcement and examination purposes. 68 FR 58974, 59009 and 59011 (2003). The rule currently does not require anticipated arrival information for food articles arriving by international mail.

The lack of anticipated arrival information for food articles arriving by international mail results in challenges to FDA's ability to track or locate the movement of such articles. This decreases FDA's ability to prevent food articles from entering the U.S. food supply that present a public health risk or bio-terrorism threat. The additional requirement to provide the tracking number for food articles arriving by international mail will serve similar purposes that anticipated arrival information does for private delivery mail and will better enable FDA to locate and inspect food articles that present a risk to the U.S. food supply.

Description of Respondents: Persons submitting prior notice for articles of food imported or offered for import into the United States by international mail. 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.

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.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue impact on small entities. We have conducted a preliminary regulatory impact analysis in support of the proposed rulemaking.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

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 1320.11, we have published a proposed rule in the *Federal Register*,

including an analysis of burden and solicitation of public comment for the proposed information collection. Although FDA received comments on the proposed rule, none were responsive to the four collection of information topics solicited. Therefore, the estimated Paperwork Reduction Act burden for this final rule is the same as the estimated burden in the 2023 NPRM (88 FR 74939)

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 is point of contact name, business address, business phone number, and business e-mail address. 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, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate collection methods, FDA 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

Our estimate of the burden for this collection of information is as follows:

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Average No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Annual Hours
1.281(b)(10) - Information Included in Prior Notice					
One-Time Burden		1	5,460	0.5 (30 minutes)	2,730

Recurring Burden	5,460	143	780,780	0.07 (4 minutes)	54,655
Total					57,385

Based on 2021 fiscal year data from our Online Reporting Analysis Decision Support System, we estimate that 26,200 persons submit prior notice through PNSI. We assume 5,460, or roughly 20 percent, are importing or offering for import articles of food by international mail. The requirement to submit tracking information applies only to persons importing or offering for import articles of food by international mail. The number of prior notices for international mail entries per respondent per year ranges from 1 to approximately 5,000. The average number of prior notice submissions for international mail entries per person per year is approximately 143. Of the more than 18 million prior notices received by FDA per year, approximately 780,780 are identified as “mail.”

We estimate a one-time average burden of 30 minutes per respondent to learn the new requirement and coordinate with mail services to establish best practices for receiving and providing the information. In addition to the one-time burden, we estimate an average recurring annual burden of 4 minutes per prior notice mail submission. The one-time total burden for all the 5,460 respondents totals 2,730, and the recurring burden amounts to 54,655 hours. Therefore, we estimate the total annual burden to be 57,385 hours.

12b. Annualized Cost Burden Estimate

We estimate the annualized cost burden to respondents for this collection of information is \$4,650,480.40. 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 2025 (\$40.52/hour). To account for overhead, this cost is increased by 100 percent, which is \$81.04 per hour. Thus, the annual wage cost imposed by this collection of information is approximately \$4,650,480.40 (57,385 hours x \$81.04 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	57,385	\$81.04	\$4,650,480.40

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 PNSI.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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.