



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0118]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0520. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002--21 CFR 1.278 to 1.285

OMB Control Number 0910-0520

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 FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receives 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 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 the Agency review after FDA has 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); and § 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 additional information that indicates prior refusals by any country and also identifies the country or countries, the Agency may better identify imported food shipments that

may pose safety and security risks to U.S. consumers. This additional knowledge can further help FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States.

Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA 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 <https://www.access.fda.gov/>. Information the Agency collects in the prior notice submission includes: (1) 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. The information in an 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 reflects FDA's estimate of the reduced burden for prior notice submitted through ABI/ACS 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 FDA if information changes after the Agency 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 the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l), §§ 1.283(d) and 1.285(j) (21 CFR 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 the Agency places 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.

In the Federal Register of January 5, 2017 (82 FR 1349), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section No.	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
<u>Prior Notice Submissions</u>						
<u>Prior Notice Submitted Through ABI/ACS</u>						
1.280-1.281	None	1,700	7,647	12,999,900	0.167 (10 minutes)	2,170,983 ²
<u>Prior Notice Submitted Through PNSI</u>						
1.280-1.281	3540 ³	27,000	70	1,890,000	0.384 (23 minutes)	725,760
New Prior Notice Submissions Subtotal						2,896,743
<u>Prior Notice Cancellations</u>						
<u>Prior Notice Cancelled Through ABI/ACS</u>						
1.282	3540	7,040	1	7,040	0.25 (15 minutes)	1,760
<u>Prior Notice Cancelled Through PNSI</u>						
1.282, 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 minutes)	8,802
Prior Notice Cancellations Subtotal						10,562
<u>Prior Notice Requests for Review and Post-Hold Submissions</u>						
1.283(d), 1.285(j),	None	1	1	1	8	8
1.285(i)	None	263	1	263	1	263
Prior Notice Requests for Review and Post-Hold Submissions Subtotal						271
Total						2,907,576

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

²To 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 this total.

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

FDA received 10,450,824 prior notices through ABI/ACS during 2014; 11,282,015 during 2015; and 12,153,880 during 2016. Based on this experience, the Agency estimates that approximately 1,700 users of ABI/ACS will submit an average of 7,647 prior notices annually, for a total of 12,999,900 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hour, per notice, for a total burden of 2,170,983 hours. This estimate takes into consideration the

burden hours already counted in the information collection approval for FDA importer's entry notice (OMB control number 0910-0046), as previously discussed.

FDA received 1,529,110 prior notices through PNSI during 2014; 1,633,567 during 2015; and 1,768,790 during 2016. Based on this experience, the Agency estimates that approximately 27,000 registered users of PNSI will submit an average of 70 prior notices annually, for a total of 1,890,000 prior notices received annually. FDA estimates the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hour, per notice, for a total burden of 725,760 hours.

FDA received 7,265 cancellations of prior notices through ABI/ACS during 2014; 7,910 during 2015; and 5,948 during 2016. Based on this experience, the Agency estimates that approximately 7,040 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 7,040 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 hour, per cancellation, for a total burden of 1,760 hours.

FDA received 36,324 cancellations of prior notices through PNSI during 2014; 39,553 during 2015; and 29,743 during 2016. Based on this experience, the Agency estimates that approximately 35,208 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 35,208 cancellations received annually. FDA estimates the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 8,802 hours.

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

FDA received 235 post-hold submissions under § 1.285(i) during 2014; 218 during 2015; and 337 during 2016. Based on this experience, the Agency estimates that 263 post-hold submissions under § 1.285(i) 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, the Agency estimates a total reporting burden of 263 hours.

Dated: May 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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