Dated: December 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0179]

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 January 27, 2014.

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 *oira_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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)—Revision.

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 (FD&C Act) (21 U.S.C. 381(m)), which requires that we 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 our 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 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.'' In the **Federal Register** of May 5, 2011 (76 FR 25542), we issued an interim final rule (IFR) entitled ''Information Required in Prior Notice of Imported Food'' (2011 IFR) that implemented section 304 of FSMA and requested public comments. OMB approved the collection of information requirements of the 2011 IFR under OMB control number 0910–0683. On May 30, 2013 (78 FR 32359), we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. In this request for extension of OMB approval under the PRA, we are combining the burden hours associated with OMB control number 0910–0683 (collection entitled ''Information Required in Prior Notice of Imported Food'') with the burden hours approved under OMB control number 0910–0520 (collection entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'').

Advance notice of imported food allows us, 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. This additional knowledge can further help us 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.

Our 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 *http://www.access.fda.gov/.* Information we collect 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 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).

Much of the information collected for prior notice is identical to the information collected for our 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 of this document reflects our estimate of the reduced burden for prior notice submitted through ABI/ACS in the column labeled ''Hours 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 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.

In the **Federal Register** of November 1, 2013 (78 FR 65670) FDA published a 60-day notice requesting public comment on the proposed collection of information; no comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section No.	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions						
Prior Notice Submitted Through ABI/ACS						
1.280–1.281	None	15,000	608	9,120,000	0.167	1,523,040 [2]
Prior Notice Submitted Through PNSI						
1.280–1.281	FDA 3540 [3]	26,667	58	1,546,686	0.384	593,927
New Prior Notice Submissions Subtotal						2,116,967
Prior Notice Cancellations						
Prior Notice Cancelled Through ABI/ACS						
1.282	FDA 3540	4,098	1	4,098	0.25	1,025
Prior Notice Cancelled Through PNSI						
1.282, 1.283(a)(5).	FDA 3540	33,096	1	33,096	0.25	8,274
Prior Notice Cancellations Subtotal						9,299
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						2,126,275

[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 No. 0910–0046 are not included in this total.

[3] The term ''Form FDA 3540'' refers to the electronic submission system known as the Prior Notice System Interface (PNSI), which is available at *http://www.access.fda.gov.*

This estimate is based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years.

As previously discussed, on May 30, 2013, we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. We estimate that it would take on average about one additional minute (0.016 hours) per entry for each respondent to submit prior notice with this additional piece of information. Accordingly, we have increased our estimate of the hours per response for prior notices received through ABI/ACS from 9 minutes, or 0.15 hours, per notice, to 10 minutes, or 0.167 hours, per notice. We have also increased our estimate of the hours per response for prior notices received through PNSI from 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice, to 23 minutes, or 0.384 hours, per notice.

We received 8,570,504 prior notices through ABI/ACS during 2010; 9,054,187 during 2011; and 9,716,147 during 2012. Based on this experience, we estimate that approximately 15,000 users of ABI/ACS will submit an average of 608 prior notices annually, for a total of 9,120,000 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 hours, per notice, for a total burden of 1,523,040 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for our importer's entry notice, as previously discussed in this document.

We received 1,566,029 prior notices through PNSI during 2010; 1,498,609 during 2011; and 1,524,901 during 2012. Based on this experience, we estimate that approximately 26,667 registered users of PNSI will submit an average of 58 prior notices annually, for a total of 1,546,686 prior notices received annually. We estimate the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hours, per notice, for a total burden of 593,927 hours.

We received 4,488 cancellations of prior notices through ABI/ACS during 2010; 3,993 during 2011; and 3,812 during 2012. Based on this experience, we estimate that approximately 4,098 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 4,098 cancellations received annually through ABI/ACS. We estimate 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 1,024.5 hours, rounded to 1,025 hours.

We received 33,353 cancellations of prior notices through PNSI during 2010; 33,343 during 2011; and 32,592 during 2012. Based on this experience, we estimate that approximately 33,096 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 33,096 cancellations received annually. We estimate the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 8,274 hours.

We have not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (2010, 2011, and 2012); therefore, we estimate that one or fewer requests for review will be submitted annually. We estimate that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we have estimated a total reporting burden of 8 hours.

We have not received any post-hold submissions under § 1.285(i) in the last 3 years (2010, 2011, and 2012); therefore, we estimate that one or fewer post-hold submissions will be submitted annually. We estimate that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, we have estimated a total reporting burden of 1 hour.

Dated: December 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1147]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

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 January 27, 2014.

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0541. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (OMB Control Number 0910–0541)—Extension

As an integral part of its decisionmaking process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, we amended our regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, we no longer routinely require submission of information about the manufacturing and production of our regulated articles. We also have eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, we have provided guidance that contains sample formats to help the industry submit a claim of categorical exclusion or an EA to the Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion, (2) what must a claim of categorical exclusion include by regulation, (3) what is an EA, (4) when is an EA required by regulation and what format should be used, (5) what are extraordinary circumstances, and (6) what suggestions does CFSAN have for preparing an EA? CFSAN encourages the industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the