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.

[FR Doc. 2013–30996 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

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

efficiency of the review process. Although alternative approaches may be used, if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of October 28, 2013 (78 FR 64218), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. However, the comment was beyond the scope of the collection of information's four topics that are being solicited. Therefore, it will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part 25; Environmental impact considerations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 25.32(i)	42	1	42	1	42
§ 25.32(o)	1	1	1	1	1
§ 25.32(q)	2	1	2	1	2
Total					45

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

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested for each of these three categorical exclusions in this guidance is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30998 Filed 12–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1558]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information request regarding the guidance for industry and FDA staff entitled ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.''

DATES: Submit either electronic or written comments on the collection of information by February 25, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the