TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

| 21 CFR Section | FDA Form No. | No. of Respondents | Annual Frequency per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| *Domestic* | | | | | | |
| 1.230–1.233 | FDA 3537[2] | 13,560 | 1 | 13,560 | 2.5 | 33,900 |
| *Foreign* | | | | | | |
| 1.230–1.233 | FDA 3537 | 23,370 | 1 | 23,370 | 8.5 | 198,645 |
| **New Facility Registration Subtotal** | | | | | | 232,545 |
| **Previously Registered Facilities-Updates (Form 3537) and Cancellations (Form 3537a)** | | | | | | |
| 1.234 | FDA 3537 | 118,530 | 1 | 118,530 | 1 | 118,530 |
| 1.235 | FDA 3537a | 6,390 | 1 | 6,390 | 1 | 6,390 |
| **Updates or Cancellations to Existing Registration Subtotal** | | | | | | 124,920 |
| **Total Hours Annually** | | | | | | 357,465 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at *http://www.access.fda.gov*.

This estimate is based on FDA's experience and the average number of new facility registrations, updates and cancellations received in the past 3 years. FDA received 12,681 new domestic facility registrations during 2006; 14,629 during 2007; and 13,378 during 2008. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 13,560. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the agency's registration regulations will require a burden of approximately 2.5 hours per average domestic facility registration. The average domestic facility burden hour estimate of 2.5 hours takes into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new domestic facility registrations is estimated to be 33,900 hours (13,560 x 2.5 hours).

FDA received 25,513 new foreign facility registrations during 2006; 23,302 during 2007; and 21,281 during 2008. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 23,370. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the agency's registration regulations will require a burden of approximately 8.5 hours per average foreign facility registration. The average foreign facility burden hour estimate of 8.5 hours includes an estimate of the additional burden on a foreign facility to obtain a U.S. agent, and takes into account that for some foreign facilities the respondent completing the registration may not be fluent in English and/or not have readily available Internet access. Thus, the total annual burden for new foreign facility registrations is estimated to be 198,645 hours (23,370 x 8.5 hours).

FDA received 114,199 updates to facility registrations during 2006; 128,070 during 2007; and 113,318 during 2008. Based on this experience, FDA estimates that it will receive 118,530 updates annually. FDA also estimates that updating a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. Thus, the total annual burden for updating all registrations is estimated to be 118,530 hours.

FDA received 5,703 cancellations of facility registrations during 2006; 5,578 during 2007; and 7,888 during 2008. Based on this experience, FDA estimates the annual number of cancellations will be 6,390. FDA also estimates that cancelling a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

Dated: March 11, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–5656 Filed 3–15–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0118]**

### Agency Information Collection Activities; Proposed Collection; 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 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 collection provisions of FDA's regulations requiring that the agency receive prior notice before food is imported or offered for import into the United States.

**DATES:** Submit written or electronic comments on the collection of information by May 17, 2010.

**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:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**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 validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**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)—Extension**

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 act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278, 1.279, 1.280, 1.281, and 1.282 of FDA's regulations (21 CFR 1.278, 1.279, 1.280, 1.281, 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 FDA review after an article of food has been refused admission under section 801(m)(1) of the act or placed on hold under section 801(l) of the 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. 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's 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 (PN) System Interface (Form FDA 3540). The term "Form FDA 3540" refers to the electronic system known as the FDA PN System Interface, which is available at *http://www.access.fda.gov*. Prior notice must be submitted electronically using either ABI/ACS or the FDA PN System Interface. Information collected by FDA 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 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 FDA's importer's entry notice, which has been approved under OMB control number 0910–0046. The information in FDA's 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 are already accounted for in the importer's entry notice information collection, and the burden hour analysis in table 1 of this document reflects 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 if information changes after FDA 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 FDA has confirmed a prior notice submission for review (§ 1.282(a)(1)(i), (a)(1)(ii), and (a)(1)(iii)). In the event that an article of food has been refused admission under section 801(m)(1) of the act or placed on hold under section 801(l), §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA review and the information required to be included in a request for review. In the event that an article of food has been placed under hold under section 801(l) of the act, § 1.285(i) sets forth the procedure for and the information to be included in a post-hold submission.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | FDA Form No. | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| Prior Notice Submissions | | | | | | |
| Prior Notice submitted through ABI/ACS | | | | | | |
| 1.280, 1.281 | None | 6,500 | 1,290 | 8,385,000 | 0.15 | 1,257,750[2] |
| Prior Notice submitted through PN System Interface | | | | | | |
| 1.280, 1.281 | FDA 3540[3] | 21,500 | 73 | 1,569,500 | 0.37 | 580,715[2] |
| New Prior Notice Submissions Subtotal | | | | | | 1,838,465 |
| Prior Notice Cancellations | | | | | | |
| Prior Notice cancelled through ABI/ACS | | | | | | |
| 1.282 | FDA 3540 | 6,500 | 3 | 19,500 | 0.25 | 4,875 |
| Prior Notice cancelled through PN System Interface | | | | | | |
| 1.282, 1.283(a)(5) | FDA 3540 | 21,500 | 3 | 64,500 | 0.25 | 16,125 |
| Prior Notice Cancellations Subtotal | | | | | | 21,000 |
| 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 | | | | | | 1,859,474 |

[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 system known as the FDA PN System Interface, which is available at *http://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.

In the **Federal Register** of November 7, 2008 (73 FR 66294), FDA and CBP issued the prior notice final rule, which finalized the prior notice interim final rule (IFR) (October 10, 2003, 68 FR 58974)). From the IFR to the final rule, FDA removed a few of the required prior notice data elements. Specifically, submitters no longer need to include the fax number of the submitter and transmitter, the anticipated border crossing, the country of the carrier, or the 6-digit HTS code in their prior notices. Other changes include the addition of the registration number of the transshipper for articles of food for transshipment, storage and export, or manipulation and export; flexibility in submitting the registration number and the city and country of the manufacturer and shipper instead of full addresses of these entities; and the option of submitting the tracking number for articles of food arriving by express consignment instead of anticipated arrival information when the prior notice is submitted through the PN System Interface (73 FR 66294 at 66402). Accordingly, FDA has reduced its estimate of the hours per response for prior notices received through ABI/ACS from 10 minutes, or 0.167 hours, per notice, to 9 minutes, or 0.15 hours, per notice. FDA has also reduced its estimate of the hours per response for prior notices received through the PN System Interface from 23 minutes, or 0.384 hours, per notice, to 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice.

FDA received 8,144,419 prior notices through ABI/ACS during 2007; 8,266,200 during 2008; and 5,221,549 as of August 26, 2009. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 1,290 prior notices annually, for a total of 8,385,000 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/ACS to be 9 minutes, or 0.15 hours, per notice, for a total burden of 1,257,750 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA's importer's entry notice, as previously discussed in this document.

FDA received 1,744,287 prior notices through the PN System Interface during 2007; 1,662,033 during 2008; and 989,708 as of August 26, 2009. Based on this experience, FDA estimates that approximately 21,500 registered users of the PN System Interface will submit an average of 73 prior notices annually, for a total of 1,569,500 prior notices received annually through the PN System Interface. FDA estimates the reporting burden for a prior notice submitted through the PN System Interface to be 22 minutes, or 0.366

hours (rounded to 0.37 hours), per notice 22 minutes, or 0.366 hours (rounded to 0.37 hours), per notice, for a total burden of 580,715 hours.

FDA received 16,215 cancellations of prior notices through ABI/ACS during 2007; 16,673 during 2008; and 16,045 as of August 26, 2009. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 2.64 (rounded to 3) cancellations annually, for a total of 19,500 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 hours, per cancellation, for a total burden of 4,875 hours.

FDA received 58,345 cancellations of prior notices through the PN System Interface during 2007; 63,779 during 2008; and 55,019 as of August 26, 2009. Based on this experience, FDA estimates that approximately 21,500 registered users of the PN System Interface will submit an average of 3.24 (rounded to 3) cancellations annually, for a total of 64,500 cancellations received annually through the PN System Interface. FDA estimates the reporting burden for a cancellation submitted through the PN System Interface to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 16,125 hours.

FDA has not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (2007 through August 26, 2009); 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, FDA has estimated a total reporting burden of 8 hours.

FDA has not received any post-hold submissions under § 1.285(i) in the last 3 years (2007 through August 26, 2009); therefore, the agency estimates that one or fewer post-hold submissions 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, FDA has estimated a total reporting burden of 1 hour.

Dated: March 11, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–5655 Filed 3–15–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0124]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by the Family Smoking Prevention and Tobacco Control Act

**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information pertaining to the submission of smokeless tobacco rotational warning plans under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act), as amended by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

**DATES:** Submit written or electronic comments on the collection of information by May 17, 2010.

**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:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@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 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 validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### Requirements under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by the Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Smokeless Tobacco Act (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires that manufacturers, packagers, importers, distributors, and retailers (in limited circumstances) of smokeless tobacco products include one of four specified health warning label statements on product packages and in advertisements.[1] The Smokeless Tobacco Act, as amended, also requires smokeless tobacco product manufacturers, importers, distributors, and certain retailers to submit a plan to FDA specifying the method to rotate, display, and distribute the specified health warning label statements

[1] The warnings themselves disclose information completely supplied by the Federal Government. As such, the disclosure does not constitute a "collection of information" as it is defined in the regulations implementing the PRA, nor, by extension, do the financial resources expended in relation to it constitute paperwork "burden." See 5 CFR 1320.3(c)(2).