

TABLE 1.—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN<sup>1</sup>—Continued

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
701.11	1,518	24	36,432	1	36,432
701.12	1,518	24	36,432	1	36,432
701.13	1,518	24	36,432	1	36,432
Total					141,174

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

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: A declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

According to the 2001 census, there are 1,518 cosmetic product establishments in the United States (U.S. Census Bureau, <http://www.census.gov/epcd/susb/2001/us/US32562.HTM>). FDA calculates label design costs based on stockkeeping units (SKUs) because each SKU has a unique product label. Based on data available to the Agency and on communications with industry, FDA estimates that cosmetic establishments will offer 94,800 SKUs for retail sale in 2010. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that FDA discusses in this information collection, § 701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§ 701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. FDA estimates that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the Agency's experience with other products, FDA estimates that cosmetic establishments may redesign up to one-third of SKUs

per year. Therefore, FDA estimates that the annual frequency of response will be 21 (31,878 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

FDA estimates that each of the required label elements may add approximately 1 hour to the label design process. FDA bases this estimate on the hour burdens the Agency has previously estimated for food, drug, and medical device labeling and on the Agency's knowledge of cosmetic labeling. Therefore, FDA estimates that the total hour burden on members of the public for this information collection is 141,174 hours per year.

Dated: May 25, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## 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 June 28, 2010.

**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 e-mailed to [oira\\_submission@omb.eop.gov](mailto: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:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**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—(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 through 1.282 of FDA's regulations (21 CFR 1.278 through 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 under 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) (§ 1.280(a)(2)). 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) through (a)(1)(iii)). In the event that an article of food has been refused admission under section 801(m)(1) or placed under hold under section 801(l) of the act, §§ 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.

In accordance with 5 CFR 1320.8(d), in the **Federal Register** of March 16, 2010 (75 FR 12549), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter, containing multiple comments, in response to this notice. These comments were outside the scope of the four collection of information topics on which the notice solicits public comment and, thus, will not be addressed here.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section No.	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
<b>Prior Notice Submissions</b>						
Prior Notice submitted through ABI/ACS						
1.280 through 1.281	None	6,500	1,290	8,385,000	0.15	1,257,750 <sup>2</sup>
Prior Notice submitted through PN System Interface						
1.280 through 1.281	FDA 3540 <sup>3</sup>	21,500	73	1,569,500	0.37	580,715
New Prior Notice Submissions Subtotal						1,838,465
<b>Prior Notice Cancellations</b>						
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 and 1.283(a)(5)	FDA 3540	21,500	3	64,500	0.25	16,125
Prior Notice Cancellations Subtotal						21,000
<b>Prior Notice Requests for Review and Post-hold Submissions</b>						
1.283(d) and 1.285(j)	None	1	1	1	8	8

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section No.	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1.285(i)	None	1	1	1	1	1
Prior Notice Requests for Review and Post-hold Submissions Subtotal						9
<b>Total Hours Annually</b>						1,859,474

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

<sup>2</sup> 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 number 0910-0046 are not included in this total.

<sup>3</sup> 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.

On November 7, 2008, FDA and CBP issued the prior notice final rule (73 FR 66294), which finalized the prior notice interim final rule (IFR) (68 FR 58894, October 10, 2003). 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 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 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 has also reduced its estimate of the hours per response for prior notices received through the PN System Interface from 23 minutes to 22 minutes. 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, 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: May 24, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Administration; Matching Requirements on Grants Awarded Under Children's Bureau Funding Opportunity Announcement for Fiscal Year 2010

**AGENCY:** Division of Grants Policy, Office of Financial Services, Office of Administration, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

**ACTION:** Notice.

*CFDA Number:* 93.648.