Sections 201, 502, 601, 602, 603, 701, and 704 of the act (21 U.S.C. 321, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the act or misbranded under section 602 of the act.

FDA's cosmetic labeling regulations are published in part 701 (21 CFR part 701). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

FDA's cosmetic labeling regulations remain unchanged by this document. FDA is publishing this document in compliance with the PRA. This document does not represent any new regulatory initiative.

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

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
701.3	1,518	21	31,878	1	31,878
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

[1] 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: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5657 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–0119]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities 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 the agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in 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.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.230–1.235 (OMB Control Number 0910–0502)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 415 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230–1.235 of FDA's regulations (21 CFR 1.230–1.235) set forth the procedures for registration of food facilities. Information provided to FDA under these regulations will help the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply.

Description of Respondents: The respondents to this information collection include owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register.

FDA's regulations require that each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States register with FDA using Form FDA 3537 (§ 1.231). 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*. The agency strongly encourages electronic registration because it is faster and more convenient. The system the agency has developed can accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week. A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are filled in. However, paper registrations will be accepted. Form FDA 3537 is available for download for registration by mail, fax, or CD–ROM. Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations that FDA will have to enter manually.

Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories identified in § 170.3 (21 CFR 170.3), unless "most/all" human food categories "or none of the above mandatory categories" is selected as a response; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, facilities are encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal.

In addition to registering, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture/process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

FDA estimates the burden of complying with the information collection provisions of the agency's regulations for food facility registration as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
New Facilities						

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]

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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