Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Total	463		522,815		278,765.95

* Includes an estimated 2,500 kidney transplant patients transplanted prior to the initiation of the data system.

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 25, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–12964 Filed 5–27–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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*. All comments should be identified with the OMB control number 0910–0502. 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.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002— (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 through 1.235 of FDA's regulations (21 CFR 1.230 through 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).

In the **Federal Register** of March 16, 2010 (75 FR 12547), 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 the notice.

(Comment 1) One comment contended that it was unnecessary for companies to have to register their facilities with FDA.

(Response) FDA disagrees. In the Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule (see the **Federal Register** of Feburary 3, 2003 (68 FR 5378 at 5387 to 5413)), FDA asserted that requiring registration of manufacturers/ processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways. One, by requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain. Two, if FDA is aware of a specific food threat, a registration database would make FDA better able to inform the facilities potentially affected by the threat. Three, FDA would be able to deploy more efficiently its domestic compliance and regulatory resources. Four, FDA inspectors, using prior notice and registration, would be better able to identify shipments offered for import for inspection.

Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. Persons who might attempt to intentionally contaminate the U.S. food supply would be deterred, by the creation of additional evidence that might be used against them, from starting a business in the food supply chain. Persons who might intentionally contaminate the food supply but refuse to register would be subject to criminal and civil sanctions and, if foreign, would risk having their product held at a U.S. port. With emergency contact information and product categories, FDA can quickly call or e-mail the emergency contact at both domestic and foreign facilities that may be targeted by a specific food threat. If FDA suspects a particular product is at risk, the agency can quickly identify which facilities to contact. This rapid communication ability will allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination of food.

(Comment 2) One comment stated that facilities that hold food should not be required to register.

(Response) FDA disagrees with the suggested change to its regulations. The agency's regulations implement the food facility registration requirements in section 305 of the Bioterrorism Act, 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.

(Comment 3) One comment stated that, to lessen the burden of the regulation, FDA should not require firms to update their registration information, but only to cancel their registration when the facility stops holding food.

(Response) FDA disagrees with the suggested change to its regulations. Requiring registrants to update the registration information for their facilities will directly enhance FDA's ability to satisfy the agency's obligation to maintain an up-to-date list of registered facilities, as required by section 415(a)(4) of the act. FDA has balanced the greater efficiency of the agency's having specific information regarding food manufactured/processed, packed, or held at each facility against the burden on facilities to submit initially and update this information as circumstances change. Without updated emergency contact information and product categories, the agency's ability to quickly call or e-mail the emergency contact at facilities that may be targeted by a specific food threat would be negatively impacted.

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
New Facilities						
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: May 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13003 Filed 5–27–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0120]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

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 (the PRA).

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*. All comments should be identified with the OMB control number 0910–0599. 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.

Cosmetic Labeling Regulations—(OMB Control Number 0910–0599)—Extension

The Federal Food, Drug, and Cosmetic Act (the act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. 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 notice. FDA is publishing this notice in compliance with the PRA. This notice does not represent any new regulatory initiative.

In the **Federal Register** of March 16, 2010 (75 FR 12546), 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 the notice. One comment expressed strong support for the labeling of cosmetics. Additional comments were outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here.

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