comments and recommendations must be submitted in one of the following ways by January 25, 2013.'' has been extended to February 1, 2013.''

Dated: January 16, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–01172 Filed 1–18–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Procedures for Requests from Tribal Lead Agencies to use Child Care and Development Fund (CCDF) Funds for Construction or Major Renovation of Child Care Facilities.

OMB No.: 0970–0160.

Description: The Child Care and Development Block Grant Act, as amended, allows Indian Tribes to use Child Care and Development Fund (CCDF) grant awards for construction and renovation of child care facilities. A tribal grantee must first request and receive approval from the Administration for Children and Families (ACF) before using CCDF funds for construction or major renovation. This information collection contains the statutorily-mandated uniform procedures for the solicitation and consideration of requests, including instructions for preparation of environmental assessments in conjunction with the National Environmental Policy Act. The proposed draft procedures update the procedures that were originally issued in August 1997 and last updated in April 2010. Respondents will be CCDF tribal grantees requesting to use CCDF funds for construction or major renovation.

Respondents: Tribal Child Care Lead Agencies acting on behalf of Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Construction or Major Renovation of Tribal Child Care Facilities	5	1	20	100

Estimated Total Annual Burden Hours: 100.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–01117 Filed 1–18–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0065]

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 either electronic or written comments on the collection of information by March 25, 2013.

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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@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 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) (Pub. L. 107–188) added section 415 to the Federal Food, Drug, and Cosmetic Act (the FD&C 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 helps the Agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support FDA enforcement activities and to screen imported food shipments. Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection, to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. If a facility is not registered or the registration for a facility is not updated when necessary, FDA may not be able to contact the facility and may not be able to target import inspections effectively in case of a known or potential threat to the food supply or other food-related emergency, putting consumers at risk of consuming hazardous food products that could cause serious adverse health consequences or death.

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.* 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.

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; 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; 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).

The FDA Food Safety Modernization Act (FSMA) (Public Law 111–353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, and to require facilities required to register with FDA to renew such registrations biennially. Section 415(a)(2) of the FD&C Act (21 U.S.C. 350d(a)(2)), as amended by FSMA, also provides that, when determined necessary by FDA ''through guidance,'' a food facility is required to submit to FDA information about the general food category of a food manufactured, processed, packed or held at such facility, as determined appropriate by FDA, including by guidance. These amendments took effect October 1, 2012. To comply with this statutory deadline, FDA initially obtained OMB approval of the following additional collection of information requirements under the emergency processing provisions of the PRA:

- Modification of food facility registration forms to include the following mandatory fields: The email address for the contact person of a domestic facility and the email address of the U.S. agent for a foreign facility, an assurance that FDA will be permitted to inspect the facility, and specific food categories as identified in the guidance document entitled, ''Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories'' (77 FR 64999, October 24, 2012) (section 415(a)(2) of the FD&C Act); and
- The requirement that registered facilities submit registration renewals to FDA biennially (section 415(a)(3) of the FD&C Act (21 U.S.C. 350d(a)(3)).

Food Facility Registration, in conjunction with advance notice of imported food, helps FDA act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Food Facility Registration provides FDA with information about facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information helps FDA and other authorities determine the source and cause of the event. In addition, the registration information enables FDA to notify more quickly the facilities that might be affected by the outbreak. See Interim Final Rule entitled, ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (68 FR 58894, at 58895; October 10, 2003).

Implementation of the new FSMA requirements described previously helps enable FDA to quickly identify and remove from commerce an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause

serious adverse health consequences or death to humans or animals. FDA uses the information collected under these provisions to help ensure that such food products are quickly and efficiently removed from the market.

Description of Respondents: Respondents to this collection of information are 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section and/or section of FD&C Act	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New Facilities						
Domestic						
§ 1.230–1.233 and section 415 of the FD&C Act.	FDA 3537 [2].	11,080	1	11,080	2.7	29,916
Foreign						
§ 1.230–1.233 and section 415 of the FD&C Act.	FDA 3537	19,900	1	19,900	8.9	177,110
New Facility Registration Subtotal	.....	.....	.....	.....		207,026
Previously Registered Facilities						
Updates under § 1.234 and section 415 of the FD&C Act.	FDA 3537	118,530	1	118,530	1.2	142,236
Cancellations under § 1.235	FDA 3537a.	6,390	1	6,390	1	6,390
Biennial renewal of registration required by section 415 of the FD&C Act.	FDA 3537	224,930	1	224,930	0.5 (30 mins.)	112,465
Updates, Cancellations or Biennial Renewals Subtotal.	.....	.....	.....	.....		261,091
Total Hours Annually	.....	.....	.....	.....		468,117

[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 12,011 new domestic facility registrations during 2010, 10,646 during 2011, and 10,584 during 2012. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 11,080. 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. We estimate that the FSMA-required additional information for new facility registrations will require an additional 12 minutes (0.2 hour) per response for domestic facilities. The average domestic facility burden hour estimate of 2.7 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 29,916 hours (11,080 × 2.7 hours).

FDA received 20,598 new foreign facility registrations during 2010; 20,009 during 2011 and 19,092 during 2012. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 19,900. 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. We estimate that the FSMA-required additional information for new facility registrations will require an additional 24 minutes (0.4 hour) per response for foreign facilities. The average foreign facility burden hour estimate of 8.9 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 177,110 hours (19,900 × 8.9 hours).

Based on its experience, FDA estimates that the average annual number of updates to facility registrations will remain unchanged at 118,530 updates annually over the next 3 years. 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. We estimate that the FSMA-required additional information for updates will require an additional 12 minutes (0.2 hour) per response. Thus, the total annual burden of submitting updates to facility registrations is estimated to be 142,236 hours (118,530 × 1.2 hours).

Based on its experience, FDA estimates that the average annual number of cancellations of facility registrations will remain unchanged at 6,390 cancellations annually over the next 3 years. 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. FSMA did not change the required information for cancellations. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

We estimate that the new biennial registration required by FSMA, which will require the submission of certain new data elements and the verification and possible updating of other information rather than re-entering all information, will require 30 minutes (0.5 hour) per response, including time for the new FSMA-required information. FDA estimates that, on an annualized basis, the number of biennial registrations submitted over the next 3 years will be 224,930. This estimate is based on the number of currently registered firms (449,860) divided by two. Thus, the total annual burden for biennial registration is estimated to be 112,465 hours (224,930 x 0.5 hours).

Dated: January 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01157 Filed 1–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1240]

Draft Guidance for Industry and Food and Drug Administration Staff; Submissions for Postapproval Modifications to a Combination Product Approved Under Certain Marketing Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA.'' This draft guidance intends to provide the underlying principles to determine the type of marketing submission that may be required for postapproval changes to a combination product that is approved under one marketing application, i.e., a biologics license application (BLA), a new drug application (NDA), or a device premarket approval application (PMA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 22, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your request. The draft guidance may also be obtained by mail by calling the Office of Combination Products at 301–796–8930. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products, Food and Drug Administration, Bldg. 32, rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA.'' This document provides guidance to industry and FDA staff on the underlying principles to determine the type of marketing submission that may be required for postapproval changes to a combination product, as defined in 21 CFR 3.2(e), that is approved under one marketing application, i.e., a BLA, an NDA, or a device PMA.

The regulatory standards for when to provide a postmarket submission for a change to an approved, stand-alone drug, device, or biological product or its manufacturing process are described in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 505, 506A, and 515 of the FD&C Act), the Public Health Service Act (PHS Act) (section 351 of the PHS Act), and FDA's associated regulations (21 CFR 314.70, 601.12, and 814.39). As a general matter, these provisions set forth similar criteria for when a submission for a changed article is required, but do not expressly address submissions for changes to an approved combination product.

This draft guidance intends to provide clarity in the postapproval change requirements and consistency in the type of postmarket submission to provide for a change to a combination product approved under one marketing application (BLA, NDA, or PMA). In particular, the draft guidance document provides tables that may be helpful in determining what type of submission to provide for a postmarket change to a constituent part of a combination product where the regulatory identity of the modified constituent part differs from the application type under which the combination product is approved.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 for NDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for BLAs have been approved