Administration for Children and Families, Office of Administration, Office of Information Services, 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.*

Respondents: State and Territory CCDF Lead Agencies (56).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–118	56	0.50	162.50	4,550

Estimated Total Annual Burden Hours: 4,550.

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. 2013–03813 Filed 2–19–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meeting

AGENCY: Administration for Children and Families' Office of Head Start (OHS).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of two 1-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, 640(l)(4)].

DATES: March 19, 2013, and June 11, 2013.

ADDRESSES: 2013 Office of Head Start Tribal Consultation Sessions will be held at the following locations: Tuesday, March 19, 2013—Albuquerque, New Mexico—Hotel Albuquerque at Old Town, 800 Rio Grande Boulevard NW., Albuquerque, NM 87104; and Tuesday, June 11, 2013—Spokane, Washington—DoubleTree Spokane City Center, 322 N. Spokane Falls Court, Spokane, WA 99201.

FOR FURTHER INFORMATION CONTACT: Robert Bialas, Regional Program Manager, Region XI, Office of Head Start, email *Robert.Bialas@acf.hhs.gov* or phone (202) 205–9497. Additional information and online meeting registration is available at *eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) announces Office of Head Start (OHS) Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. As much as possible, the OHS Tribal Consultations are being scheduled in conjunction with other tribal events. The Consultation in Albuquerque is being held in conjunction with the 32nd Native American Child and Family Conference (NACFC), presented by the Southwest Consortium of Indian Head Start Programs, Inc. The Consultation in Spokane is being held in conjunction with the 23rd Annual National Indian Head Start Directors Association (NIHSDA) Training Conference. Such scheduling is an effort to minimize the burden of travel for tribal participants. Tribal Consultation dates and locations for other parts of the country, including Alaska, will be announced at a later date.

The agenda for the scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian/Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2012 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for these Consultation Sessions should contact Robert Bialas at *Robert.Bialas@acf.hhs.gov.* Proposals must be submitted at least 3 days in advance of each session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. The letter should be submitted at least 3 days in advance of the Consultation Sessions to Robert Bialas via fax at 866–396–8843. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Sessions will be prepared and made available within 45 days of the

Consultation Sessions to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Robert Bialas at *Robert.Bialas@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Sessions will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for the Consultation Sessions has been sent to tribal leaders via email and posted on the Early Childhood Learning and Knowledge Center Web site at *eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013*.

Dated: February 11, 2013.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2013–03795 Filed 2–19–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

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 March 22, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0322. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Environmental Impact Considerations—(OMB Control Number 0910–0322)—Revision

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.''

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4327) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(c) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting Agency action require the submission of a claim for categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in significant environmental impact. Sections 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statues for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the Agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. When the Agency finds that no significant environmental effects are expected, the Agency prepares a finding of no significant impact.

In the **Federal Register** of September 28, 2012 (77 FR 59619), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments that were PRA related were received from one commenter.

(Comment 1) The commenter indicated that FDA underestimates the hours required to complete an environmental assessment for tobacco products, and that FDA's 12 hours burden estimate per response is substantially underestimated. The commenter said, based on the commenter's experience, an environmental assessment for tobacco products should take approximately 80 hours to complete.

(Response 1) FDA agrees with this comment. Upon further review of the number of hours required to complete an environmental assessment for tobacco products, FDA has determined that 12 hours is too low an estimate and has revised the burden estimate per response for completing an environmental assessment for tobacco products from 12 to 80 hours. This revision was based upon revisiting this estimate with the Center for Tobacco Products staff and this comment. Rethinking the time to prepare an environmental assessment for tobacco products resulted in revising the burden per response to 80 hours.

(Comment 2) The commenter also encouraged the Agency to establish categorical exclusions for environmental assessments for tobacco product submittals under section 905(j) of the