Confederated Salish and Kootenai Tribes	Pablo, MT	25,000
White Earth Band of Chippewa Indians	White Earth, MN	25,000

The program expansion supplement awards will support expanded services to identify and analyze systems to improve effectiveness and efficiencies across early childhood programs, share action plans to improve outcomes, continue the implementation of and expand the development of concrete community plans, and develop peer learning relationships.

DATES: September 30, 2013–September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Shannon Rudisill, Director, Office of Child Care, 901 D Street SW., Washington, DC 20447. Telephone: (202) 401–6984; Email: *shannon.rudisill@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: One of the stated goals of the Tribal MIECHV program is to support and strengthen cooperation and coordination, and promote linkages among various programs that serve pregnant women, expectant fathers, young children, and families, resulting in the establishment of coordinated and comprehensive early childhood systems in grantee communities.

The activities of the four grantees are expected to result in models for tribal early learning systems that can be replicated in other tribal communities as well as to expand the reach and impact of technical assistance activities for the four participating tribal grantees.

In addition, the supplements will expand the reach and impact of technical assistance efforts by supporting and strengthening existing coordination and collaboration activities and expanding the scope of additional such activities in tribal communities.

Statutory Authority: Awards are supported by section 511(h)(2)(A) of Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act, Public Law 111–148, also known as the Affordable Care Act (ACA).

Shannon L. Rudisill,

Director, Office of Child Care.

[FR Doc. 2013–24863 Filed 10–22–13; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

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 November 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 0910–0298. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39 (OMB Control Number 0910–0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of June 26, 2013 (78 FR 38349), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 170.39	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Threshold of regulation for substances used in food-contact articles	7	1	7	48	336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past three years. The annual hours per response reporting estimate of 48 hours is based on information received from representatives of the food packaging and processing industries and Agency records.

FDA estimates that approximately 7 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) (OMB control number 0910–0495) in that the use of a substance exempted by the Agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the Agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at *http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm*. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the Agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: October 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24804 Filed 10–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1170]

Draft Guidance for Industry on Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; 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 entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in all phases of development of direct-acting antiviral (DAA) drugs for the treatment of chronic hepatitis C. This guidance revises and replaces a previous draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment'' issued on September 14, 2010.

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 December 23, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft 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: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in all phases of development of DAA drugs for the treatment of chronic hepatitis C. This guidance revises the draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment'' issued in September 2010. Significant changes in this revision include:

- Details on phase 2 and phase 3 trial design options for the evaluation of interferon (IFN)-free and IFN-containing regimens in treatment-naïve and treatment-experienced populations, including DAA-experienced populations.
- Revised primary endpoint to sustained virologic response at 12 weeks post-treatment cessation.
- Greater emphasis on DAA drug development in special populations including trial design options for human immunodeficiency virus/hepatitis C virus co-infected patients, patients with decompensated cirrhosis, and patients pre- or post-liver transplant.
- More details on clinical virology considerations for DAA drugs.