vaccines; (3) advises the Director of the NVP in the implementation of Sections 2102 and 2103 of the PHS Act; and (4) identifies annually for the Director of the NVP the most important areas of governmental and non-governmental cooperation that should be considered in implementing Sections 2101 and 2103 of the PHS Act.

NVAC was established on July 30, 1987. As a Federal advisory committee, NVAC is governed by the provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.) To comply with the guidelines under FACA, NVAC has been re-chartered at the appropriate intervals since it was established. On July 27, 2011, the Assistant Secretary for Health approved for NVAC to be rechartered. The new charter was effected and filed with the appropriate Congressional offices and Library of Congress on July 30, 2011. The rechartering of NVAC gives authorization for the Committee to continue to operate until July 30, 2013.

A copy of the NVAC charter is available on the website for the National Vaccine Program Office at http://www.hhs.gov/nvpo/nvac. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is http://fido.gov/facadatabase.

Bruce Gellin, Deputy Assistant Secretary for Health (Vaccines and Immunization), Director, National Vaccine Program Office.

[FR Doc. 2011–20197 Filed 8–8–11; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request


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Estimated Total Annual Burden Hours: 378.

Additional Information:

Copies of the proposed collection may be obtained by writing to the 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. E-mail 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, E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis
Reports Clearance Officer.

[FR Doc. 2011–20105 Filed 8–8–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

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

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of one-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, Section 6401(l)(4)).

DATES: October 17 and 19, 2011.

ADDRESSES: 2011 Office of Head Start Tribal Consultation Sessions will be held at the following locations: Monday, October 17, 2011—Seattle, Washington—Westin Seattle, 1900 5th Avenue, Seattle, WA 98101; Wednesday, October 19, 2011—Anchorage, Alaska—Sheraton Anchorage Hotel & Spa, 401 East 6th Avenue, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Camille Loya, Acting Regional Program Manager Region XI, e-mail Camille.Loya@acf.hhs.gov or phone (202) 401–5964. Additional information and online meeting registration is available at http://www.headstartresourcecenter.org.

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 in Region X and in Alaska. The Consultation Session for Region X will take place Monday, October 17, 2011, in Seattle, Washington. The Consultation Session for the State of Alaska will take place Wednesday, October 19, 2011, in Anchorage, Alaska, immediately preceding the annual Alaska Federation of Natives convention. We are convening the OHS Tribal Consultations in conjunction with other Tribal Leader events in order to minimize the financial and travel burden for participants.

The agendas for both scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and 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 2010 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for the Seattle or Anchorage Consultation Sessions should contact Camille Loya at Camille.Loya@acf.hhs.gov or (202) 205–9721 (fax). Other representatives of Tribal Governments and Native nonprofit organizations are welcome to attend as observers.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, Section 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 three days in advance of the Consultation Session to Camille Loya at (202) 205–9721 (fax). Other representatives of Tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session or within 30 days after the meeting. Oral testimony and comments from the Consultation Session will be summarized in the report without attribution, along with topics of concern and recommendations. Hotel and logistical information for all Consultation Sessions has been sent to Tribal leaders via e-mail and posted on the Head Start Resource Center Web site at http://www.headstartresourcecenter.org.

Dated: August 1, 2011.

Yvette Sanchez Fuentes,
Director, Office of Head Start.

BILING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2011–N–0116]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Medical Device 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.

DATES: Fax written comments on the collection of information by September 8, 2011.

ADDRESS: 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 0910–0485. 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., P150–400B, 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.

Medical Device Labeling Regulations—
(OMB Control Number 0910–0485)—(Extension)

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a regulatory action. Certain provisions under section 502 require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices, on the labels or labeling for the devices.

Section 502(b) of the FD&C Act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may however, grant an exemption, if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case, as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves or the devices, on the label or labeling for the devices to health professionals and consumers. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the FD&C Act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations under parts 800, 801, and 809 are derived from requirements of section 502 of the FD&C Act, which provides in part, that a device shall be misbranded if among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

Reporting Burden

Sections 800.10(a)(3) and 800.12(c) require that the label for contact lens cleaning solutions bear a prominent statement alerting consumers of the tamper-resistant feature. Further, § 800.12 requires that packaged contact lens cleaning solutions contain a tamper-resistant feature, to prevent malicious adulteration.