

the address below, no later than 5 p.m. on *September 12, 2012*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: August 7, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2012-19689 Filed 8-10-12; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Tribal Consultation Meeting**

**AGENCY:** Office of Head Start (OHS), Administration for Children and Families, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to the Improving Head Start for School Readiness Act of 2007, notice is hereby given of a one-day Tribal Consultation Session 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 this Consultation Session 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.

**DATES:** October 15, 2012 and October 17, 2012.

**ADDRESSES:** 2012 Office of Head Start Tribal Consultation Session will be held at the following locations: Monday, October 15, 2012—Portland, Oregon—Westin Portland, 750 SW Alder Street, Portland, OR 97205; and Wednesday, October, 17, 2012—Anchorage, Alaska—Hilton Anchorage Hotel, 500 West Third Avenue, Anchorage, AK 99501.

**FOR FURTHER INFORMATION CONTACT:** Ann Linehan, Deputy Director, Office of Head Start, email [Ann.Linehan@acf.hhs.gov](mailto:Ann.Linehan@acf.hhs.gov) or phone (202) 205-8579. 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 15, 2012, in Portland, Oregon. The Consultation Session for the State of Alaska will take place Wednesday, October 17, 2012, in Anchorage, Alaska, immediately preceding the annual Alaska Federation of Natives convention. As much as possible, OHS Tribal Consultations are scheduled in conjunction with other Tribal Leader events. This is done in an effort to minimize the financial and travel burden for participants.

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 AI/AN 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 2011 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for the Oklahoma City Consultation Session should contact Ann Linehan at [Ann.Linehan@acf.hhs.gov](mailto:Ann.Linehan@acf.hhs.gov). Proposals must be submitted at least three days in advance of the session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Session 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 Ann Linehan at (202) 205-9721 (fax). Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 90 days of the Consultation Session 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 Ann Linehan at [Ann.Linehan@acf.hhs.gov](mailto:Ann.Linehan@acf.hhs.gov) either prior to

the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for the Consultation Session has been sent to tribal leaders via email and posted on the Head Start Resource Center Web site at <http://www.headstartresourcecenter.org>.

Dated: July 23, 2012.

**Yvette Sanchez Fuentes,**

*Director, Office of Head Start.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-D-0523]

**Draft Guidance for Industry and Food and Drug Administration Staff; Refuse To Accept Policy for 510(k)s; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Refuse to Accept Policy for 510(k)s." The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a premarket notification (510(k)) submission is administratively complete, which determines whether it should be accepted for substantive review. This guidance is applicable to 510(k)s reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). This draft guidance is not final nor is it in effect at this time.

**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 September 27, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Refuse to Accept Policy for 510(k)s" to the Division of Small Manufacturers, International and Consumer Assistance, Center for