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.


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 or phone (202) 205–8579. Additional information and online meeting registration is available at http://www.headstartresourcecenter.org.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Draft Guidance for Industry and Food and Drug Administration Staff; Refuse To Accept Policy for 510(k)s; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Refuse to Accept Policy for 510(k)s.” The purpose of this document is to explain the procedures and criteria FDA intends to use in determining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) 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 This draft guidance is not final nor is it in effect at this time.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...