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.*

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* 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.* 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* 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.

[FR Doc. 2012–19587 Filed 8–10–12; 8:45 am]

BILLING CODE 4184–40–P

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

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Geeta Pamidimukkala, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1564, Silver Spring, MD 20993–0002, 301–796–6453; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

I. Background

The purpose of the 510(k) acceptance review is to make a threshold determination whether a submission is administratively complete, which determines whether it should be accepted for substantive review to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act, 21 U.S.C. 360c(i). To find a device substantially equivalent under section 513(i) of the FD&C Act, FDA must find that it has the same intended use as the predicate device, and either: (1) Has the same technological characteristics as the predicate device or (2) has different technological characteristics, as defined at section 513(i)(1)(B), and the submission contains information, including appropriate clinical or scientific data if necessary, that demonstrates the device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness than the predicate.

The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a 510(k) submission is administratively complete and should be accepted for substantive review. This guidance document provides updated information to two existing guidance documents entitled ''Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy'' issued on June 30, 1993, and ''510(k) Refuse to Accept Procedures, 510(k) Memorandum K94–1'' issued on May 20, 1994. Upon issuance as a final guidance document, this guidance will replace those documents.

To further focus the Agency's review resources on complete applications, which will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible, we have modified the 1993 and 1994 guidances. For example, we have modified the 510(k) refuse to accept policy to include an early review against specific acceptance criteria and to inform the submitter within the first 15 calendar days of receipt of the submission if the submission is administratively complete, or if not, to identify the missing element(s). In order to enhance the consistency of our acceptance decisions and to help submitters better understand the types of information FDA needs to conduct a substantive review, this guidance, including the checklists included in the appendices, clarifies the necessary elements and contents of a complete 510(k) submission. These elements are applicable to all devices reviewed through the 510(k) notification process in CDRH and CBER and have been compiled into checklists for use by FDA review staff.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the refuse to accept policy for 510(k)s. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

To receive ''Refuse to Accept Policy for 510(k)s,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1793 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19744 Filed 8–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0842]

Division of Cardiovascular Devices 30-Day Notices and Annual Reports; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Division of Cardiovascular Devices 30-Day Notices and Annual Reports.'' This public workshop will be cosponsored with Advanced Medical Technology Association (AdvaMed). The purpose of