Indian Tribes (or a consortium of Indian Tribes), Tribal Organizations, or Urban Indian Organizations to conduct an early childhood home visiting program. Specifically, the legislation provides for a 3 percent set-aside of the total Maternal, Infant, and Early Childhood Home Visiting Program appropriation (authorized in Section 511(j)) for discretionary competitive grants to Tribal entities.

Summary: The Administration for Children and Families (ACF), Office of Child Care (OCC) announces the award of five Fiscal Year 2011 Tribal Maternal, Infant, and Early Childhood Home Visiting single source grants to the following:

Eastern Band of Cherokee Indians: $205,000. Cherokee, NC.

Eastern Band of Cherokee Indians will provide home visiting services to children under the age of 5 and their families on the Qualla Boundary.

Native American Health Center, Inc.: $227,000. Oakland, CA.

Native American Health Center, Inc. is an urban Tribal organization that will provide home visiting services to the American Indian and Alaska Native (AIAN) population in a five-county region in Northern California, which includes Oakland and San Francisco.

Riverside-San Bernardino County Indian Health, Inc.: $348,000. Banning, CA.

Riverside-San Bernardino County Indian Health, Inc. is a tribally controlled health care organization that will provide home visiting services to approximately 2,000 families on 10 tribal reservations in Riverside and San Bernardino Counties.

Taos Pueblo: $340,000. Taos, NM.

At the Taos Pueblo, there are currently no services for infants under the age of 18 months and their parents. The award will allow the Taos Pueblo to provide home visiting services for up to 300 families in order to complete the continuum of services for children, aged birth to age 5, and their families.

United Indians of All Tribes Foundation: $182,000. Seattle, WA.

This is an urban Indian organization that will provide home visiting services to the AIAN population in King County, WA, which represents more than 100 different Tribal entities.

The Tribal Maternal, Infant, and Early Childhood Home Visiting single source awards will support the grantees in conducting community needs assessments; planning for and implementation of high-quality, culturally relevant, evidence-based home visiting programs in at-risk Tribal communities for pregnant women and families with young children aged birth to kindergarten entry; and participate in research and evaluation activities to build the knowledge base on home visiting among American Indian and Alaska Native populations.

It is expected that the five grantees will continue with their projects for the remainder of a projected five-year project period by implementing home visiting activities for which grantees may receive noncompetitive continuation awards. Home visiting programs are intended to promote outcomes such as improvements in maternal and prenatal health, infant health, and child health and development; reduced child maltreatment; improved parenting practices related to child development outcomes; improved school readiness; improved family socio-economic status; improved coordination of referrals to community resources and supports; and reduced incidence of injuries, crime, and domestic violence.

Dates: July 1, 2011–June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Carol Gage, Office of Child Care, 370 L'Enfant Promenade SW., Washington, DC 20047, *Telephone:* 202–690–6243, *e-mail: carol.gage@acf.hhs.gov*.

Dated: July 21, 2011.

Shannon L. Rudisill,

Director, Office of Child Care.

[FR Doc. 2011–18960 Filed 7–26–11; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0453]

Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device; 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 ''510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device.'' The recommendations in this guidance document are intended to describe when a new 510(k) should be submitted for a change or modification to a legally marketed device. 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 October 25, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device'' 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. 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: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background

Since the amendment of the Federal Food, Drug, and Cosmetic Act by the Medical Device Amendments of 1976, FDA has attempted to define with greater clarity when a modification to an existing medical device would trigger the requirement that a new premarket notification (510(k)) be submitted to the Agency and cleared prior to marketing. FDA regulations state in 21 CFR 807.81(a)(3) when a 510(k) must be submitted, but the language used in this regulation sometimes leads to varying interpretations of when a 510(k) is required for a device modification. In order to address this issue, FDA issued in 1997 the guidance document entitled ''Deciding When To Submit a 510(k) for a Change to an Existing 510(k)''; however, regulatory changes such as the implementation of the Quality System Regulation have occurred since that time, and medical device technology has evolved.

In addition, in September 2009, FDA convened an internal 510(k) Working Group to conduct a comprehensive assessment of the 510(k) process. The 510(k) Working Group evaluated the 510(k) program with the goal of strengthening the program and improving the consistency in the Agency's decisionmaking process. In August 2010, the Center for Devices and Radiological Health (CDRH) published two documents in consideration of the comments made at the public meeting and the Agency's preliminary assessment of the program. These documents are titled ''CDRH Preliminary Internal Evaluations—Volume I: 510(k) Working Group Preliminary Report and Recommendations'' and ''CDRH Preliminary Internal Evaluations—Volume II: Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations'' (*http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm*). In January 2011, CDRH published the ''Plan of Action for Implementation of 510(k) and Science Recommendations'' (*http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf*). One of the action items identified in the Plan of Action included publication of an update to the 1997 Device Modifications Guidance.

The recommendations in this draft guidance document are consistent with longstanding FDA policy for when a modification to a device does and does not require the submission of a 510(k). The guidance has been updated, however, to address issues associated with software and other rapidly changing technologies, and to provide greater clarity about changes that do not trigger the need for a new premarket submission. This guidance uses examples of modifications to devices involving such technologies to illustrate changes that require a new 510(k), and changes that may simply be documented in accordance with a manufacturer's existing Quality System without prompting the need for a new 510(k) submission. FDA believes increased certainty about the regulatory consequences of device modifications is critical to facilitating advancements in device technology. FDA is specifically interested in seeking comments on the changes described, types of changes that are not covered by this document but should be, and illustrative examples of types of changes.

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 when a new 510(k) should be submitted for a change or modification to a legally marketed device. 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.regulations.gov.* To receive the draft guidance entitled ''510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device,'' you may either send an e-mail 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 previously 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 56.115 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

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. It is no longer necessary to send two copies of mailed 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: July 21, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–18923 Filed 7–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Organ Transplantation (ACOT).

Date and Times: August 23, 2011, 1 p.m. to 5 p.m.; August 24, 2011, 8:30 a.m. to 5 p.m.

Place: Georgetown University Hotel and Conference Center, 3800 Reservoir Road, NW., Washington, DC 20057.

Status: The meeting will be open to the public.

Purpose: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

Agenda: The Committee meeting will convene at 1 p.m. The Committee will hear reports from two ACOT Work Groups: Declining Rates of Donation/Geographical