Dated: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration Pediatric Medical Devices Workshop; Notice of Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following workshop: FDA Pediatric Medical Devices Workshop. This meeting is intended to focus on challenges in pediatric device development—namely, business planning and funding concerns; and how sponsors can most effectively interact with the FDA. The goal of this meeting is to engage and educate pediatric innovators and device industry sponsors.

This educational meeting will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will also include a ''mock'' FDA pre-submission meeting for a ''mock'' pediatric medical device, to illustrate how such encounters may transpire. In addition, attendees will have an opportunity during lunch to engage with Pediatric Device Consortia Grant Program leaders. The meeting will be recorded for subsequent posting on the FDA Web site.

Date and Time: The meeting will be held on September 24, 2012, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. For participants who cannot attend the live meeting, a recorded Web cast will be made available after the meeting.

Contact: Linda Ulrich, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm.5206, Silver Spring, MD 20993–0002, 301–796–8686, FAX: 301–847–8621, email: *megan.mcnamee@icfi.com.*

Registration: Interested participants may register for this meeting at the following Web site: *https://events-support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop.* Please note that registration for the live meeting will be limited based on available seating.

If you need sign language interpretation during this meeting, please contact Linda Ulrich at: *Linda.Ulrich@fda.hhs.gov* by August 24, 2012.

The FDA Pediatric Medical Devices Workshop is supported by FDA's Office of Orphan Product Development and will include participants from the FDA's Center for Devices and Radiologic Health.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: July 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Draft Policy on Conferring With Urban Indian Organizations

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice, with a 45-day comment period.

SUMMARY: This Notice sets forth the Indian Health Service policy for conferring with urban Indian organizations and invites comments within 45 days. In March 2010, the Indian Health Care Improvement Act was reauthorized and amended as part of the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act (together, the Affordable Care Act), Public Law 111–152. One of the changes made to the IHCIA was to create a new requirement that the IHS ''confer'' with UIOs, to the maximum extent practicable, in carrying out the Act as defined by the Indian Health Care Improvement Reauthorization and Extension Act, as enacted and amended by the Affordable Care Act.

DATES: We will consider all comments received by September 10, 2012.

ADDRESSES: Submit comments by email to *Betty.Gould@ihs.gov*; or by US mail to: Ms. Betty Gould, Regulations Officer, Indian Health Service, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ms. Phyllis Wolfe, Director, Office of Urban Indian Health Programs, Indian Health Service, 801 Thompson Avenue, Suite 200, Rockville, Maryland 20852. Telephone 301/443–4680 (This is not a toll free number).

Policy on Conferring With Urban Indian Organizations

5–26.1 Introduction

A. *Purpose.* Congress has specifically declared that it is the policy of the Nation ''to ensure the highest possible health status for Indians and urban Indians.'' 25 U.S.C. 1602(1). The U. S. Department of Health and Human Services (HHS) is committed to working with Indian and urban Indian communities to meet this policy. This policy applies to the Indian Health Service (IHS).

This Notice establishes the IHS policy and procedures for conferring with urban Indian organizations (UIOs). The IHS will use this conferring policy to ensure that the health care needs of the urban Indian population are considered at the local, Area, and national levels, when implementing and carrying out the Indian Health Care Improvement Act (IHCIA).

B. *Background.* Urban Indian organizations are a major provider of health care to urban American Indians and Alaska Natives (AI/AN) across the country. When the IHCIA was enacted into law in 1976, it identified the authorities, responsibilities, and functions of the IHS, the primary Federal Agency charged with providing health care to AI/AN. The IHCIA included the authority for the IHS to ''establish programs in urban centers to make health services more accessible to urban Indians'' [Indian Health Care Improvement Act, Title V, section 501, Pub. L. 94–437, 90 Statute (Stat.) 1400, 1410 (1976), codified at 25 United States Code (U.S.C.) 1651]. The IHS carries out this authority through contracts with and grants to UIOs. In March 2010, as part of the Affordable Care Act, Congress reauthorized and amended the IHCIA. The reauthorization of the IHCIA included a requirement that the IHS ''confer,'' to the maximum extent practicable, with UIOs in carrying out the IHCIA.

C. *Policy.* It is IHS policy to confer with UIOs, to the maximum extent practicable, whenever a ''critical event or issue,'' as defined in this Notice, arises in implementing or carrying out the IHCIA.