provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Compliance Team's request for initial CMS approval of its RHC accreditation program. This notice also solicits public comment on whether the Compliance Team's requirements meet or exceed the Medicare conditions for certification for RHC.

III. Evaluation of Deeming Authority Request

The Compliance Team submitted all the necessary materials to enable us to make a determination concerning its request for initial approval of its RHC accreditation program. This application was determined to be complete on July 26, 2013. Under section 1865(a)(2) of the Act and our regulations at § 488.8 (federal review of accrediting organizations), our review and evaluation of the Compliance Team will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Compliance Team's standards for RHC's as compared with our RHC conditions for certification.
- The Compliance Team's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of the Compliance Team's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ The Compliance Team's processes and procedures for monitoring a RHC found out of compliance with the Compliance Team's program requirements. These monitoring procedures are used only when the Compliance Team identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.7(d).

++ The Compliance Team's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ The Compliance Team's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of the Compliance Team's staff and other resources, and its financial viability.

++ The Compliance Team's capacity to adequately fund required surveys.

++ The Compliance Team's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ The Compliance Team's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 4, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–22849 Filed 9–19–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meeting

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

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of two 1-day Tribal Consultation Sessions 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 these Consultation Sessions 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 [42 U.S.C. 9835, 640(l)(4)].

DATES: October 23, 2013, and October 29, 2013.

ADDRESSES: 2013 Office of Head Start Tribal Consultation Sessions will be held at the following locations:

Wednesday, October 23, 2013—Fairbanks, Alaska—Fairbanks Princess Riverside Lodge, 4477 Pikes Landing Road, Fairbanks, AK 99709; and Tuesday, October 29, 2013—Rapid City,

South Dakota—Best Western Ramkota Hotel and Conference Center, 2111 N. LaCrosse Street, Rapid City, SD 57701.

FOR FURTHER INFORMATION CONTACT: Robert Bialas, Regional Program Manager, Region XI, Office of Head Start, email *Robert.Bialas@acf.hhs.gov* or phone (202) 205–9497. Additional information and online meeting registration is available at *http://eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.*

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. As much as possible, the OHS Tribal Consultations are being scheduled in conjunction with other tribal events. The Consultation in Fairbanks will be held in conjunction with the Alaska Federation of Natives Annual Convention. The Consultation in Rapid City will be held in conjunction with the National Indian Education Association's 44th Annual Convention and Trade Show. Such scheduling is an effort to minimize the burden of travel for tribal 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 American Indian/Alaska Native 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 2012 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for these Consultation Sessions should contact Robert Bialas at *Robert.Bialas@acf.hhs.gov.* Proposals must be submitted at least 3 days in advance of each 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, 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 3 days in advance of the Consultation Session to Robert Bialas via fax at 866–396–8843. 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 45 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 Robert Bialas at *Robert.Bialas@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 Early Childhood Learning and Knowledge Center Web site at *http://eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.*

Dated: September 16, 2013.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2013–22950 Filed 9–19–13; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1039]

Draft Guidance for Industry on Endocrine Disruption Potential of Drugs: Nonclinical Evaluation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Endocrine Disruption Potential of Drugs: Nonclinical Evaluation.'' This draft guidance provides recommendations to sponsors on the parameters that should be routinely assessed in toxicology studies for investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) regulated by the Center for Drug Evaluation and Research to determine the potential for a drug to disrupt the endocrine system. This draft guidance also discusses factors to consider in determining the need for additional studies to characterize potential endocrine disruptor properties of a drug.

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 November 19, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993–0002, 301–796–0175.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Endocrine Disruption Potential of Drugs: Nonclinical Evaluation.'' Endocrine disruptors are compounds that have the potential to interfere with some aspect of the endocrine system of an organism or its progeny. Any component of the endocrine system can be a target of endocrine disruptors, although the systems most commonly affected include the sex hormones (e.g., estrogen and androgen), the hypothalamic-pituitary-adrenal axis, the thyroid hormone, and the hormones involved in the feedback regulation of those components (e.g., gonadotropin releasing hormone and corticotropin). Changes in endocrine function can result in transgenerational effects (e.g., through epigenetic mechanisms). Epigenetic modifications are heritable changes in gene function that occur in the absence of changes to the nucleotide sequence. Because such changes can be maintained and transmitted through the germ cells, these modifications can affect gene actions across generations.

This draft guidance provides recommendations to sponsors on the