priorities in fulfillment of the agency's mission to protect and promote people's health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters to be Considered: The agenda will include discussions on NCEH/ATSDR Program Responses to BSC Guidance and Action Items; PFAS Health Related Initiatives; Expanding National Laboratory Capacity to Measure Human Exposure to Synthetic Opioids; CCARE: Controlling Childhood Asthma, Reducing Emergencies; The Intersection of Place and Health: ATSDR's Geospatial Research Analysis and Services Program (GRASP); and Social Vulnerability Index (SVI) and Ethylene Oxide. Agenda items are subject to change as priorities dictate.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–09847 Filed 5–13–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children (ACF) and Families, Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, notice is hereby given of six 1-day Tribal Consultation (TC) Sessions to be held between the HHS)/ACF, OHS 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. Six TCs will be held as part of HHS/ACF and/or ACF TC Sessions.

DATES:

June 19, 2019, from 1:00 p.m. to 3:00 p.m.
June 27, 2019, from 9:00 a.m. to 12:00 p.m.
July 10, 2019, from 1:00 p.m. to 3:00 p.m.
July 16, 2019, from 1:00 p.m. to 3:00 p.m.
August 21, 2019, from 9 a.m. to 11 a.m.
September 16, 2019, Date and time to be determined

ADDRESSES:

- June 19, 2019—Sacramento, CA (Location to be provided at a later date)
- June 27, 2019—National Indian Head Start Directors Association, Scottsdale, AZ (Location to be provided at a later date)
- July 10, 2019—Spokane, WA (Location to be provided at a later date)
- July 16, 2019—Washington, DC (Location to be provided at a later date)
- August 21, 2019—Denver, CO (Location to be provided at a later date)
- September 16, 2019—Temecula, CA (Location to be provided at a later date)

FOR FURTHER INFORMATION CONTACT: Todd Lertjuntharangool, Regional Program Manager, Region XI/AIAN, Office of Head Start, email *Todd.Lertjuntharangool@acf.hhs.gov,* or phone (202) 205–9503. Additional information and online meeting registration will be available at *http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2019.*

SUPPLEMENTARY INFORMATION: In accordance with the Improving Head Start for School Readiness Act of 2007, Public Law 110–134 [42 U.S.C. 9835, § 640(l)(4)], ACF announces OHS tribal consultations for leaders of tribal governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS tribal consultations in Sacramento, California; Scottsdale, Arizona; Spokane, Washington; Washington, DC; Denver, Colorado; and Temecula, California will be organized around the statutory purposes of Head Start tribal consultations related to meeting the needs of American Indian and 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 the 2018 OHSTCs.

The consultation sessions will be conducted with elected or appointed leaders of tribal governments and their designated representatives. Designees must have a letter from the tribal government authorizing them to represent the tribe. Tribal governments must submit the designee letter at least 3 days in advance of the consultation sessions to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov.* Other representatives of tribal organizations and Native non-profit organizations are welcome to attend as observers.

A detailed report of each consultation session will be prepared and made available within 45 days of the consultation sessions 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 Todd Lertjuntharangool at *Todd.Lurtjuntharangool@acf.hhs.gov* either prior to each consultation session or within 30 days after each meeting. OHS will summarize oral testimony and comments from the consultation sessions in each report without attribution, along with topics of concern and recommendations.

Dated: May 7, 2019.

Deborah Bergeron

Director, Office of Head Start.

[FR Doc. 2019–09927 Filed 5–13–19; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0154]

Considerations in Demonstrating Interchangeability With a Reference Product; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product.'' This guidance is intended to

assist sponsors in demonstrating that a proposed therapeutic protein product is interchangeable with a reference product for the purposes of submitting a marketing application or supplement under the Public Health Service Act (PHS Act). This guidance is one in a series of guidances that FDA has developed to implement the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

DATES: The guidance was posted to the Agency's website on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0154 for ''Considerations in Demonstrating Interchangeability With a Reference Product.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6522, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Considerations in Demonstrating Interchangeability With a Reference Product.'' This guidance is intended to assist sponsors in demonstrating that a proposed therapeutic protein product (proposed interchangeable product) is interchangeable with a reference product for the purposes of submitting a marketing application or supplement under section 351(k) of the PHS Act (42 U.S.C. 262(k)).

Section 351(k) of the PHS Act sets forth the requirements for an application for a proposed biosimilar product and for an application or a supplement for a proposed interchangeable product. Specifically, section 351(k)(4) provides that upon review of an application submitted under section 351(k), or any supplement to such application, FDA will determine the biological product to be interchangeable with the reference product if FDA determines that the information submitted in the application (or supplement) is sufficient to show that the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Section 351(i) of the PHS Act states that the term interchangeable or interchangeability, in reference to a

biological product that is shown to meet the standards described in section 351(k)(4), means that the biological product may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

This guidance gives an overview of important scientific considerations in demonstrating interchangeability with a reference product, including:

- The data and information recommended to support a demonstration of interchangeability
- Considerations for the design and analysis of a switching study or studies to support a demonstration of interchangeability
- Considerations regarding the comparator product in a switching study or studies
- Abbreviated considerations for developing presentations, container closure systems, and delivery device constituent parts for proposed interchangeable products

This guidance finalizes the draft guidance issued on January 18, 2017. Changes made to the guidance took into consideration the comments received. FDA provided changes to clarify its recommendations for demonstrating interchangeability with the reference product. FDA intends to provide more detailed recommendations on the data and information recommended to support the proposed interchangeable product's presentation and related issues in a separate guidance.

In the **Federal Register** of January 18, 2017 (82 FR 5579), FDA announced the availability of the draft guidance for industry ''Considerations in Demonstrating Interchangeability With a Reference Product.'' FDA requested comment on the following questions: (1) Are there considerations in addition to comparability assessments that FDA should consider in regulating post-approval manufacturing changes of interchangeable products and (2) how, if at all, should the Agency consider conditions of use that are licensed for the reference product after an interchangeable product has been licensed. The comments submitted in response to these questions are being considered; FDA will address these topics in future guidance, as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Considerations in Demonstrating Interchangeability With a Reference Product.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This 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 under 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information under 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information under section 351(k) of the PHS Act have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: May 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10001 Filed 5–10–19; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records Notice

AGENCY: Office of the Secretary of Health and Human Services (OS), Department of Health and Human Services (HHS).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, HHS is revising a department-wide system of records, System No. 09–90–1601 titled Outside Experts Recruited for Non-FACA Activities, to add records about outside consultants used by HHS' Administration for Children and Families, Office of Trafficking in Persons (ACF/OTIP).

DATES: The modified system of records is effective June 13, 2019, with the exception of the new and revised routine uses. The new and revised routine uses will be effective 30 days after publication of this notice, unless comments are received that warrant a revision to this notice. Comments should be submitted within 30 days of publication, but may be made at any time.

ADDRESSES: The public should submit written comments by mail or email to Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Bldg., Ste. 729H, 200 Independence Ave. SW, Washington, DC 20201, or *beth.kramer@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: General questions about the modified system of records may be submitted by mail or email to Beth Kramer, HHS Privacy Act Officer, FOIA/PA Division, Hubert H. Humphrey Bldg., Ste. 729H, 200 Independence Ave. SW, Washington, DC 20201, or *beth.kramer@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Explanation of Modifications Made to System No. 09–90–1601

This department-wide system of records covers records about individuals outside the HHS workforce who serve or are considered for service on mission-related committees and other activities (such as peer review programs) which require specific expertise or experience but are not subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App., *et seq.* The system of records has been modified to add the following records maintained by the Administration for Children and Families' Office on Trafficking in Persons (ACF/OTIP):

- *Consultants on Office on Trafficking in Persons (OTIP) projects.* ACF/OTIP contractors arrange for outside consultants to be used in OTIP programs (in addition to peer review programs) when technical assistance is needed in conferences, meetings, and evaluation projects that involve a specialized area of research, review, or advice.

The ACF/OTIP consultant records are similar in type and function to the other records currently covered by System No. 09–90–1601; *i.e.,:*

- *Curricula Vitae of Consultants to the National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC/NCHS) (formerly covered under SORN 09–20–0168).* This program maintains records about individuals with special expertise, training, and professional experience who may be enlisted to assist CDC/NCHS as consultants. The records are used by CDC/NCHS to select individuals to participate in