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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration for Native Americans; Notice of Meeting

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of Tribal Consultation.

SUMMARY: The Department of Health and Human Services, Administration for Children and Families (ACF) will host a Tribal Consultation to consult on ACF programs and tribal priorities.

DATES: September 13, 2018.

ADDRESSES: Capital Skyline Hotel, 10 "I" (eye) Street SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jeannie Hovland, Commissioner, Administration for Native Americans and Deputy Assistant Secretary for Native American Affairs at 202-401-5156, by email at anacommissioner@acf.hhs.gov or by mail at 330 C Street SW, MS-4126, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: In accordance with the ACF Tribal Consultation Policy, ACF announces tribal consultation with tribal leaders operating ACF programs.

The consultation 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 session to the Administration for Native Americans at anacommissioner@acf.hhs.gov. Other representatives of tribal organizations and Native non-profit organizations are welcome to attend as observers. A report of the consultation session will be prepared and made available at the following website address within 45 days after the closing of the consultation session. Tribes wishing to submit written testimony should send it to anacommissioner@acf.hhs.gov either prior to the consultation session or within 30 days after the meeting. ACF

will summarize oral testimony and comments from the consultation session along with topics of concern and recommendations.

ACF has identified the following topics for consultation:

Family First Services Act

Title IV-E Planning Grants—What barriers are preventing Tribes from applying for the grant

Office of Head Start annual consultation TANF and Welfare reform

The ACF Tribal Consultation Session will begin at 9:00 a.m. on September 13 and continue throughout the day until all discussions have been completed. To help both you and the ACF Principals prepare for this consultation, planning teleconference calls will be held:

Wednesday, August 22, 2018 @4:00 p.m.–4:30 p.m. (EST)

Thursday, August 23, 2018 @4:00 p.m.–4:30 p.m. (EST)

Tuesday, August 28, 2018 @4:00 p.m.–4:30 p.m. (EST)

The call-in number and passcode are: 866-769-9393 passcode: 4449449#.

The purpose of the planning calls will be to identify individuals who will provide oral testimony to ACF, solicit for tribal moderators and identify specific topics of interest so we can ensure that all appropriate individuals are present.

For any tribe unable to attend in person, ACF will provide a webinar link. Please contact our 1-877-922-9ANA (1-877-922-9262) for the webinar information.

We have set up a registration for all participants whether attending in person or by webinar. The registration address is: www.regonline.com/2018acftribalconsultation. If you plan on providing testimony, please include the name of the office(s) you wish to address.

Jeannie Hovland,

Deputy Assistant Secretary for Native American Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Announcement of Intent To Issue one OPDIV-Initiated Supplement to BCFS Health and Human Services Under the Standing Announcement for Residential (Shelter) Services for Unaccompanied Children, HHS-2017-ACF-ORR-ZU-1132

AGENCY: Unaccompanied Alien Children's (UAC) Program, Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S Department of Health and Human Services (HHS).

ACTION: Notice of intent to issue one OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, TX under the UAC Program.

SUMMARY: ACF, ORR, announces the intent to issue one OPDIV-Initiated Supplement to BCFS Health and Human Services, San Antonio, TX in the amount of \$28,003,926. ORR has been identifying additional capacity to provide shelter for potential increases in apprehensions of Unaccompanied Children at the U.S. Southern Border. Planning for increased shelter capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter for Unaccompanied Alien Children referred to its care by the Department of Homeland Security (DHS). To ensure sufficient capacity to provide shelter to unaccompanied children referred to HHS, BCFS proposed to provide ORR with 850 beds in an expedited manner.

DATES: Supplemental award funds will support activities through September 13, 2018.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Director, Division of Children's Services, Office of Refugee Resettlement, 330 C Street SW, Washington, DC 20447. Phone: 202-401-4997. Email: DCSProgram@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: ORR is continuously monitoring its capacity to shelter the unaccompanied children referred to HHS, as well as the information received from interagency partners, to inform any future decisions or actions.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing program and its services through this

supplemental award is a key strategy for ORR to be prepared to meet its responsibility to provide shelter for Unaccompanied Children referred to its care by DHS and so that the U.S. Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C. D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Elizabeth Leo,

Grants Policy Specialist, Division of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2608]

Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public meeting entitled “Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control (PQ/CMC).” This public meeting is intended to provide members of the pharmaceutical industry and other interested stakeholders an opportunity to discuss with FDA, and provide input on, topics and issues related to standardized data for electronic submission of PQ/CMC data, as detailed in the 2017 **Federal**

Register notice (FRN), “Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies.” FDA will use the information from the public meeting to improve the usability of the proposed data standards.

DATES: The public meeting will be held on October 19, 2018, from 9 a.m. to 4 p.m. Submit either electronic or written comments on this public meeting by November 16, 2018.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. Docket comments previously submitted to the FRN (Docket No. FDA–2017–N–2166, <https://www.federalregister.gov/a/2017-14456>) noted in the **SUMMARY** section, should not be resubmitted, as these are already under consideration.

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–2018–N–2608 for “Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control; Public Meeting.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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