

approved under OMB control number 0938-0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: April 12, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016-09301 Filed 4-21-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award a Single-Source Program Expansion Supplement Grant to BCFS Health and Human Services in San Antonio, TX

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice of award of a single-source program expansion supplement grant to BCFS Health and Human Services (BCFS) in San Antonio, TX.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of a single-source program expansion supplement grant for \$5,820,000 to BCFS Health and Human Services (BCFS) in San Antonio, TX, under the Unaccompanied Children's (UC) Program to support a program expansion supplement.

The expansion supplement grant will support the need to increase shelter capacity to accommodate the increasing numbers of UCs being referred by DHS.

BCFS has a network of trained, qualified emergency staff able to bring on board and operate emergency beds in short timeframe. BCFS provides residential services to UC in the care and custody of ORR, as well as services to include counseling, case management, and additional support services to the family or to the UC and their sponsor when a UC is released from ORR's care and custody.

DATES: Supplemental award funds will support activities from October 1, 2015 through September 30, 2016.

FOR FURTHER INFORMATION CONTACT:

Jalyn Sualog, Director, Division of Children's Services, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: DCSProgram@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: While the number of referrals, to the Unaccompanied Children Program in FY 2015, was below the total referrals from FY 2014, ORR has seen a change to recent referral trends. The UC program has seen an increase in the numbers of UC referred for placement since January 2015. FY15 was the first fiscal year, in the history of the UC program, in which there were eight (11) consecutive months of steadily increasing referrals. During FY 15, the largest total referrals occurred during August, with over 4,300 referrals, and these high referral numbers continued into the month of September with 4,172 referrals. In October and November, 2015, the DCS program has received referrals for initial placements for 10,158 unaccompanied children. ORR has experienced a steadily increasing census of UC in care, with longer average length of stay. This increase, in UC referred for placement, has increased the need for additional shelter beds.

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 the service requirements and the urgent need for expansion of services. The program's ability to avoid a buildup of children waiting, in Border Patrol stations, for placement in shelters, can only be accommodated through the expansion of the existing program and its services through the supplemental award.

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.

Christopher Beach,

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

[FR Doc. 2016-09383 Filed 4-21-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Scientific Evidence in Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) is announcing a public workshop entitled "Scientific Evidence in Development of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Subject to Premarket Approval. The purpose of the public workshop is to identify and discuss scientific considerations and challenges to help inform the development of HCT/Ps subject to premarket approval, including stem cell-based products.

DATES: The public workshop will be held on September 8, 2016, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/aboutfda/workingatfda/buildingsandfacilities/whiteoakcampusinformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION: The purpose of the public workshop is to identify and discuss scientific considerations and challenges to help inform the development of HCT/Ps subject to premarket approval, including stem cell-based products.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the rescheduling of a part 15 public hearing to September 12 and 13, 2016, to obtain input on four issued draft guidance

documents relating to the regulation of HCT/Ps. FDA will provide a summary of the workshop at the part 15 public hearing.

Registration: Persons (including FDA employees) seeking to view the public workshop via Adobe Connect or who wish to attend in person must register at <http://www.eventbrite.com/o/food-and-drug-administration-fda-6730245227> on or before August 1, 2016, and provide complete contact information, including name, title, affiliation, email, and phone number. There is no registration fee for the public workshop. Early registration is recommended because seating is limited and is on a first-come, first-served basis. There will be no onsite registration.

If you need special accommodations due to a disability and/or have registration questions, please contact Tasha Johnson or Pauline Cottrell at CBERPublicEvents@fda.hhs.gov (Subject line: FDA SEDHC workshop).

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm492499.htm>.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-09373 Filed 4-21-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1206]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Ebola Zaire Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Ebola Zaire virus in response to the Ebola virus outbreak in West Africa. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by OraSure Technologies, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro

diagnostic device. The Authorization follows the September 22, 2006, determination by then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security. On the basis of such determination, the Secretary of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic devices for detection of Ebola virus, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of March 4, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT:

Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the