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 Children referred to its care by the Department of Homeland Security (DHS).

The expansion supplement grants will support the need to increase shelter capacity to accommodate the increasing numbers of UCs being referred by DHS. Both grantees 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 US 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. CV85–4544R(J)(C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–145), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–R(J)(C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of the Award of Two Single-Source Program Expansion Supplement Grants Under the Unaccompanied Children’s (UC) Program**

**AGENCY:** Office of Refugee Resettlement, ACF, HHHS.

**Organization**

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<td>BCFS Health and Human Services</td>
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**


**Use of International Standard ISO 10993–1, ‘Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process”; Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHHS.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “Use of International Standard ISO 10993–1, ‘Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.”’ FDA has developed this guidance document to assist industry in preparing Premarket Applications (PMAs), Humanitarian Device Exceptions (HDEs), Investigational Device Applications (IDEs), Premarket Notifications (510(k)s), and de novo requests for medical devices that come into direct contact or indirect contact with the human body in order to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body.

The purpose of this guidance is to provide further clarification and updated information on the use of International Standard ISO 10993–1, “Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process” to