

Desk Officer for the Administration for Children and Families.

Robert Sargis,
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

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, HHS.

ACTION: Notice of award of two single-source program expansion supplement grants under the Unaccompanied Children’s (UC) Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of two single-source program expansion supplement grants for a total of \$16,476,723 under the Unaccompanied Children’s (UC) Program.

Organization	Location	Amount
BCFS Health and Human Services	San Antonio, TX	\$9,525,387
Southwest Key, Inc	Austin, TX	6,951,336

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 the service requirements and the urgent need for expansion of services. The grantees provide 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: Jallyn 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: 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 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. CV85-4544RJK (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, Office of Administration, Office of Financial Services, Division of Grants Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0350]

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, HHS.

ACTION: Notice of availability.

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

support applications to FDA. This guidance supersedes Office of Device Evaluation (ODE) Blue Book Memorandum #G95-1 (1995), entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing.'"

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2013-D-0350 for "Use of International Standard ISO 10993-1, 'Biological

evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.'" Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk

management process'" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jennifer Goode, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1212, Silver Spring, MD 20993-0002, 301-796-6374.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to assist industry in PMAs, HDEs, IDEs, 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 support applications to FDA. This guidance supersedes ODE Blue Book Memorandum #G95-1 (1995), entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing.'"

The scope of this document is limited to the biological evaluation of sterile and non-sterile medical devices that come into direct or indirect contact with the human body and covers the following topics: Use of risk assessments for biocompatibility evaluations for a proposed medical device; use of ISO 10993-1 and the FDA-modified matrix to determine the relevant biocompatibility endpoints for an evaluation; general biocompatibility testing considerations, including test article preparation; specific considerations for the following testing: Cytotoxicity, sensitization, hemocompatibility, pyrogenicity, implantation, genotoxicity, carcinogenicity, reproductive and developmental toxicity, and degradation assessments; chemical assessment recommendations; and considerations for labeling devices as "-free."

A draft of this guidance was made available in the **Federal Register** on

April 23, 2013, and the comment period closed on July 22, 2013. The final guidance was revised in response to the comments to emphasize use of risk assessment and leveraging of prior information within a submission to potentially reduce the need for new biocompatibility testing.

Commenters also requested additional details regarding biocompatibility testing of devices in contact with gas pathways and color additives used in medical devices. FDA has determined that these concepts would be appropriately addressed in separate guidance documents and have therefore been removed from this final guidance.

II. Significance of Guidance

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 Use of International Standard ISO 10993-1, "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process." 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process'" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1811 to identify the guidance you are requesting.

IV. 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 in 21 CFR part 58 have been approved under OMB control number 0910-0119;

the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

Dated: June 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Pediatric Clinical Investigator Training; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development are announcing a 2-day public workshop entitled "Pediatric Clinical Investigator Training." The purpose of this workshop is to provide investigators with training and expertise in designing and conducting clinical trials in pediatric patients that will lead to appropriate labeling. Although we have learned a lot about conducting pediatric trials over the past two decades, there are still challenges that need to be addressed. The training

course is intended to provide investigators with: (1) A clear understanding of some of the challenges of studying products in the pediatric population, including: Pediatric study design, neonates, biomarkers, endpoints, orphan drugs and rare disease trial design, formulations; (2) an overview of extrapolation as it relates to the pediatric population; and (3) an overview of ethically appropriate methods related to the design of clinical trials in the pediatric population.

DATES: The public workshop will be held on September 12 and 13, 2016, from 8 a.m. to 4 p.m. Registration to attend the workshop should be completed by September 6, 2016. (See the **SUPPLEMENTARY INFORMATION** section for instructions).

ADDRESSES: This public workshop will be held at the DoubleTree Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, terrie.crescenzi@fda.hhs.gov; or Betsy Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, elizabeth.sanford@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) made permanent the pediatric initiatives, Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act, which have stimulated pediatric research over the past two decades. The National Institutes of Health section of BPCA legislation, however, is due for reauthorization in 2017. Though much progress has been made, pediatric trials for the purpose of developing product use information are still performed less frequently than adult trials. As such, current standards for trials are much more oriented to adult scientific, ethical, and clinical processes. This situation is due, in part, to the fact that pediatric trials have both scientific challenges and unique attributes and requirements which must be met if the data are to be accepted or used by FDA.

The development of safe and effective products in the pediatric population presents many challenges. These challenges include trial design, appropriate endpoints, extrapolation of data from adults, and ethical issues. It is extremely important that pediatric