DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of Intent To Solicit and Issue One OPDIV-Initiated Supplement to Lutheran Immigration and Refugee Service, Inc. Under the Standing Announcement for Residential (Shelter) Services for Unaccompanied Children, HHS–2017–ACF–ORR–ZU–1132

AGENCY: Unaccompanied Alien Children (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 solicitation and intent to issue of one OPDIV-Initiated Supplement to Lutheran Immigration and Refugee Service, Inc., Baltimore, MD under the UAC Program.

SUMMARY: ACF, ORR announces the solicitation and intent to issue one OPDIV-Initiated Supplement to Lutheran Immigration and Refugee Service, Inc., Baltimore, MD in an amount not to exceed $1,000,000.

ORR has been identifying additional capacity for fingerprinting services for an expected increase in the number of sponsors (parents, guardians, or family friends to whom the UAC will be released) who will need to be fingerprinted. Planning for increased fingerprinting capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to ensure that the sponsor has not engaged in any activity that would indicate a potential risk to the UAC.

DATES: Supplemental award funds will support activities for up to eight months after award.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Director, Division of Unaccompanied Children Operations, Office of Refugee Resettlement, 330 C Street SW, Washington, DC 20201. Telephone: 202–401–4997; email: *jallyn.sualog@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: ORR is continuously monitoring its capacity to provide fingerprinting services to the sponsors of UAC 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 fingerprinting services to the sponsors of UAC referred to its care by DHS.

ORR plans to solicit an application from Lutheran Immigration and Refugee Service, Inc., Baltimore, MD to meet the fingerprinting needs. If the application received a favorable objective review, ORR intends to issue a supplement in the amount up to $1,000,000.

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–3079]

Request for Nominations for Voting Members on Public Advisory Panels or Committees; Device Good Manufacturing Practice Advisory Committee and the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee and device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health. This annual notice is also in accordance with the 21st Century Cures Act, which requires the Secretary to provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before October 22, 2018 will be given first consideration for membership on the Device Good Manufacturing Practice Advisory Committee and Panels of the Medical Devices Advisory Committee. Nominations received after October 22, 2018 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, contact the following persons listed in table 1:

TABLE 1—PANEL AND ADVISORY COMMITTEE CONTACTS

Primary contact person or designated federal officer	Committee/panel
Joannie Adams-White, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993, 301–796–5421, email: *Joannie.Adams-White@fda.hhs.gov*.	Medical Devices Dispute Resolution Panel.
LCDR Sara Anderson, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993, 301–796–7047, email: *Sara.Anderson@fda.hhs.gov*.	Dental Products Panel. Hematology and Pathology Devices Panel. Orthopaedic and Rehabilitation Devices Panel. Radiological Devices Panel.
Aden S. Asefa, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993, 301–796–0400, email: *Aden.Asefa@fda.hhs.gov*.	Immunology Devices Panel. Microbiology Devices Panel. Neurological Devices Panel. Ophthalmic Devices Panel. Device Good Manufacturing Practice Advisory Committee.
LCDR Patricio G. Garcia, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, 301–796–6875, email: *Patricio.Garcia@fda.hhs.gov*.	Clinical Chemistry and Clinical Toxicology Devices Panel. Gastroenterology and Urology Devices Panel. General and Plastic Surgery Devices Panel. Obstetrics and Gynecology Devices Panel.
Evella F. Washington, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993, 301–796–6683, email: *Evella.Washington@fda.hhs.gov*.	Anesthesiology and Respiratory Therapy Devices Panel. Circulatory System Devices Panel. Ear, Nose and Throat Devices Panel. General Hospital and Personal Use Devices Panel. Molecular and Clinical Genetics Devices Panel.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for vacancies listed in table 2:

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED

Committee/panel expertise needed	Vacancies	Approximate date needed
Device Good Manufacturing Practice Advisory Committee—Experts needed to provide cross-cutting scientific or clinical expertise concerning the particular issue in dispute. Vacancies include a representative of the interests of the general public and government and representatives of the interests of physicians and other health professionals.	1 General Public Representative ..... 2 Health Professional Representatives. 1 Government Representative	Immediately. 6/1/2019.
Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee—Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	1 ..... 3	Immediately. 11/30/2018.
Circulatory System Devices Panel of the Medical Devices Advisory Committee—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	3	Immediately.
Clinical Chemistry and Clinical Toxicology Panel of the Medical Devices Advisory Committee—Doctors of medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1	2/28/2019.
Dental Products Panel of the Medical Devices Advisory Committee—Dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	2	10/31/2018.
Ear, Nose and Throat Devices Panel of the Medical Devices Advisory Committee—Otologists, neurotologists, audiologists.	3	10/31/2018.
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee—Gastroenterologists, urologists, and nephrologists.	0	N/A.
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee—Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	1 ..... 1	Immediately. 8/31/2018.
General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.	3 ..... 3	Immediately. 12/31/2018.

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED—Continued

Committee/panel expertise needed	Vacancies	Approximate date needed
Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee—Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and homeostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers.	1	2/28/2019.
Immunology Devices Panel of the Medical Devices Advisory Committee—Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1 2	Immediately. 2/28/19.
Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—Experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills.	1	9/30/2018.
Microbiology Devices Panel of the Medical Devices Advisory Committee—Infectious disease (ID) clinicians (e.g. pulmonary disease specialists, sexually transmitted disease specialists, pediatric ID specialists, tropical diseases specialists) and clinical microbiologists experienced in emerging infectious diseases; clinical microbiology laboratory directors; molecular biologists with experience in in vitro diagnostic device testing; virologists; hepatologists; or clinical oncologists experienced with tumor resistance and susceptibility.	2	Immediately.
Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee—Human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, and clinical molecular genetics testing (e.g., genotyping, array comparative genomic hybridization (CGH), etc.) Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	3 2	Immediately. 5/31/2019.
Neurological Devices Panel of the Medical Devices Advisory Committee—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	1	Immediately.
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee—Perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	1 2	Immediately. 1/31/2019.
Ophthalmic Devices Panel of the Medical Devices Advisory Committee—Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	2 3	Immediately. 10/31/2018.
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee—Orthopaedic surgeons (joint, spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians.	2 1	8/31/2018. 8/31/2019.
Radiological Devices Panel of the Medical Devices Advisory Committee—Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging and image analysis.	3 3	Immediately. 1/31/2019.

I. General Description of the Committees Duties

A. Device Good Manufacturing Practice Advisory Committee

The Committee reviews regulations proposed for promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding the feasibility and reasonableness of those proposed regulations. The Committee also advises the Commissioner on any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations that is referred to the committee.

B. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices

Dispute Resolution Panel, each panel, according to its specialty area, performs the following duties: (1) Advises the Commissioner regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the FD&C Act, (7) advises on the necessity to ban a device, and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Voting Members

A. Device Good Manufacturing Practice Advisory Committee

The Committee consists of a core of nine members including the Chair. Members and the Chair are selected by the Secretary of Health and Human Services. Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public, nominees should possess appropriate qualifications to understand and contribute to the committee's work. Three of the members shall be officers or employees of any State or local government or of the Federal Government; two shall be representative of the interests of the device manufacturing industry; two shall be representatives of the interests of physicians and other health professionals; and two shall be representatives of the interests of the general public. Almost all non-Federal members of this committee serves as Special Government Employees. Members are invited to serve for overlapping terms of 4 years. The particular needs at this time for this committee are listed in table 2 of this document.

B. Panels of the Medical Devices Advisory Committee

The Medical Devices Advisory Committee (MDAC) with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. A maximum of 122 members shall be standing voting members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Non-Voting Representatives on certain panels of the MDAC. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in table 2. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2896]

Osteoarthritis: Structural Endpoints for the Development of Drugs, Devices, and Biological Products for Treatment; Draft 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 draft guidance for industry entitled ''Osteoarthritis: Structural Endpoints for the Development of Drugs, Devices, and Biological Products for Treatment.'' The purpose of this draft guidance is to assist sponsors who are developing drugs, devices, or biological products to treat the underlying pathophysiology and structural progression of osteoarthritis (OA). This draft guidance does not address improvement of symptoms of OA, such as pain or