

Linda Hitt,

ACF Certifying Officer.

[FR Doc. 2021-26102 Filed 11-26-21; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of Intent To Issue Replacement Award To Provide Residential Services (Shelter)

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of Replacement Award to Lutheran Social Services of the South Upbring (LSS Upbring).

SUMMARY: ACF, ORR announces the intent to award a Replacement Award to LSS Upbring in the amount of up to \$20,929,074 in Brownsville, Texas. On September 17, 2021, Comprehensive Health Services, LLC (CHS) relinquished a federally funded discretionary grant. Per HHS policy, ORR has identified current recipient LSS Upbring to transfer the current permanent capacity to provide shelter for apprehensions of Unaccompanied Children (UC) at the Southwest Border. The continuation of permanent capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter and appropriate services for UC referred to its care by the Department of Homeland Security. The purpose of this award is to ensure the continuation of residential services for the capacity of 76 shelter beds for UC.

DATES: The proposed period of performance is December 1, 2021–September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Stephen Antkowiak, Office of Refugee Resettlement, Division of Unaccompanied Children Operations, 330 Street SW, Washington, DC 20447. Phone: 202-260-6165. Email: stephen.antkowiak@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: ORR announces the intent to award a Replacement Award to LSS Upbring in the amount of up to \$20,929,074. This award will prevent the disruption in residential services currently available at the CHS Loma Alta location and prevent children unnecessarily pending placement from Border Patrol.

ORR has specific requirements for the provision of services. Award recipients

must have the infrastructure, licensing if applicable, experience, and appropriate level of trained staff to meet those requirements.

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 UC from the Commissioner of the former Immigration and Naturalization Service to the Director of ORR within HHS.

(B) The Flores Settlement Agreement, Case No. CV85-4544-RJK (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,

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

[FR Doc. 2021-25970 Filed 11-29-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-1146]

Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; 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 “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision-making. This guidance provides sponsors and other stakeholders with considerations when either proposing to design a registry or using an existing registry to support regulatory decision-making about a drug’s effectiveness or safety.

DATES: Submit either electronic or written comments on the draft guidance by February 28, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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-2021-D-1146 for “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” Received comments 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, 240-402-7500.

• **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 “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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993-0002, 301-796-3161, Dianne.Paraoan@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” FDA is issuing this guidance as part of its RWE Program and to satisfy, in part, the mandate under section 505F of the FD&C Act (21 U.S.C. 355g) to issue guidance about the use of RWE in regulatory decision-making. Topics covered in this guidance include:

- A registry’s fitness-for-use for regulatory decision-making, focusing on attributes of a registry that support the collection of relevant and reliable data
- Considerations when linking a registry to another data source, such as data from medical claims, electronic health records, digital health technologies, or another registry
- Considerations for supporting FDA review of submissions, including registry data

Section 3022 of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255) amended the FD&C Act to add section 505F, Utilizing Real World Evidence. This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help support or satisfy postapproval study requirements. This section also requires that FDA utilize the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in

regulatory submissions. FDA is issuing this draft guidance as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI commitment.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Real-World-Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products.” 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910-0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572. The collections of information in 21 CFR parts 310 and 314 have been approved under OMB control number 0910-0230. The collections of information in 21 CFR parts 310, 314, 600, and 803 have been approved under OMB control number 0910-0291. The collections of information in 21 CFR parts 310, 314, 600, and 803 have been approved under OMB control number 0910-0645. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910-0308. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078. The collections of information in FDA’s guidance for industry entitled “Formal Meetings with Sponsors and Applicants

for PDUFA Products” have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26006 Filed 11–29–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3233]

Request for Nominations for Voting Members on a Public Advisory Committee; Technical Electronic Product Radiation Safety Standards 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 Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in the Center for Devices and Radiological Health. Nominations will be accepted for current and upcoming vacancies effective January 1, 2022, with this notice. 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 January 31, 2022, will be given first consideration for membership on TEPRSSC. Nominations received after January 31, 2022, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by accessing FDA’s Advisory Committee Membership

Nomination Portal at <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. 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>.

FOR FURTHER INFORMATION CONTACT:

Akinola Awojope, Office of Management Services, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–636–0512, email: Akinola.Awojope@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on TEPRSSC that include five general public representatives and five government representatives.

I. General Description of the Committee’s Duties

The committee provides advice and consultation to the Commissioner of Food and Drugs (Commissioner) on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

II. Criteria for Voting Members

The committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering, applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the committee by appropriate action prior to its expiration.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home 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 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 conflicts 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: November 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26002 Filed 11–29–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0101]

Agency Information Collection Activities; Proposed Collections; Comment Request; Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collections of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA’s Prescription Drug User Fee program.

DATES: Submit either electronic or written comments on the collection of information by January 31, 2022.

ADDRESSES: 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 January 31, 2022. The <https://www.regulations.gov> electronic filing system will accept