Linda Hitt,

ACF Certifying Officer.

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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.

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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.