DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Assistance Listing Number: 93.576]

Announcement of Intent To Award an Unsolicited Cooperative Agreement to Church World Services (CWS) Headquartered in New York, NY

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

ACTION: Notice of Issuance of an Unsolicited Award.

SUMMARY: ACF, ORR, Refugee Program announces the intent to award an unsolicited cooperative agreement in the amount of up to $1,984,144 to Church World Services (CWS) in New York, NY. The purpose of this award is to provide enhanced refugee housing solutions for Afghan and Ukrainian humanitarian parolees and other ORR-eligible populations. This proposal seeks to create a local resources directory for housing, increase access to housing resources for vulnerable refugee and humanitarian parolee populations, expand innovative and replicable solutions through capacity building and key partnerships, address challenges to identifying and securing safe, affordable housing options, and provide a bank of housing resources for both refugees and community sponsors.

DATES: The proposed period of performance is September 30, 2023, to September 29, 2024.

FOR FURTHER INFORMATION CONTACT: Yimeem Vu, Program Specialist, Administration for Children and Families, Office of Refugee Resettlement, Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201. Telephone: 202–401–4825; Email: *Yimeem.Vu@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 30, 2023, Church World Services (CWS), on behalf of its Refugee Housing Solutions (RHS) initiative, submitted an unsolicited proposal to ORR for ''Enhancing Refugee Housing Solutions.'' One area of focus is directed towards eligible Ukrainian and Afghan Humanitarian Parolees and the other to all ORR-eligible populations. The first focus aims at addressing challenges in securing affordable, long-term housing for Afghan and Ukrainians through the following three means: (1) creating a 'Housing Hub' with a local resources directory and information specific to housing solutions for these populations (and translated into relevant languages); (2) increasing access to housing resources for both eligible humanitarian parolees and their sponsors; and (3) expanding innovation efforts through capacity building and key partnerships. The second area of focus aims to address challenges in securing affordable housing for all ORR-eligible populations and identify more housing options for resettlement stakeholders to utilize. This proposal seeks to achieve this by advancing innovative housing initiatives (through consultation and guidance) in collaboration with new and existing partners from nontraditional resettlement backgrounds.

RHS is currently funded by the Department of State's Bureau of Population, Refugees, and Migration (PRM) to provide Reception and Placement housing education and training, targeted assistance, piloting of three housing initiatives, expanding housing access, and reimagining refugee housing. Unlike the proposals submitted to ORR, the work done by RHS through PRM funding does not include services specifically for Ukrainian and Afghan humanitarian parolees, in addition to other ORR-populations outside of refugees. In addition, some of the concurrent work of the PRM contract will bolster the initiatives proposed to ORR, including consulting on additional innovative housing pilot programs and collection of localized resources for a housing 'hub' and directory. Further, RHS receives a subaward from ORR for housing education, training, and technical assistance through the grant to the International Rescue Committee's Switchboard. The activities of that subaward do not overlap with the suggested activities of these unsolicited proposals but could add to the bank of resources provided to newcomers and their sponsors as outlined in the first proposal. RHS is stating that their capacity to achieve the proposed activities is not possible with current levels of funding from PRM and the technical assistance subaward from ORR.

ORR intends to award CWS with one cooperative agreement for the project ''Enhancing Refugee Housing Solutions.'' After both internal and external reviews, ORR concluded with the intent to award this unsolicited proposal based on a desire to address stakeholder concerns regarding housing access and affordability and considering that the capacity of CWS would need to be expanded through additional funding to address these challenges. Various stakeholders across the nation, including grant recipient organizations, State Refugee Coordinators, local community and ethnic community-based organizations, and beneficiaries have raised concerns over the last year of housing affordability and housing stock availability for the long-term placement of resettled refugees and newcomers, particularly those with large families, and often cite housing as the number one challenge facing resettlement. Further, ORR participates with RHS through various public/private housing working groups. Through these conversations and presentations, it is apparent that RHS is unique in its mission to provide refugee housing technical assistance, identity solutions specific to refugee housing, and represent RHS partners, including all 10 national resettlement agencies, in housing concerns. However, RHS is not currently funded at a capacity that allows them to expand capabilities and advance innovative and replicable housing solutions to meet the needs of all ORR-eligible populations.

Statutory Authority: Immigration and Nationality Act section 412(c)(1)(A), 8 U.S.C. 1522(c)(1)(A).

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–2023–P–2656]

Determination That ULTRAM (Tramadol Hydrochloride) Tablets, 50 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) has determined that ULTRAM (tramadol hydrochloride) Tablets, 50 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Joan Dailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–6357, *Joan.Dailey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ULTRAM (tramadol hydrochloride) Tablets, 50 mg, is the subject of NDA 020281, held by Janssen Pharmaceuticals, Inc., and initially approved on March 3, 1995. ULTRAM is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

ULTRAM (tramadol hydrochloride) Tablets, 50 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated June 28, 2023 (Docket No. FDA–2023–P–2656), under 21 CFR 10.30, requesting that the Agency determine whether ULTRAM (tramadol hydrochloride) Tablets, 50 mg, was withdrawn from sale for reasons of safety or effectiveness. The citizen petition noted that FDA has already determined that the 100 mg tablet strength of the same drug was not discontinued for reasons of safety or effectiveness (see the **Federal Register** of April 27, 2022 (87 FR 25028)).

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ULTRAM (tramadol hydrochloride) Tablets, 50 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ULTRAM (tramadol hydrochloride) Tablets, 50 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ULTRAM (tramadol hydrochloride) Tablets, 50 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ULTRAM (tramadol hydrochloride) Tablets, 50 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21990 Filed 10–3–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4158]

User Fee Rates for Fiscal Year 2024; Change of Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that the courier address for the U.S. Bank will change. This change has a direct impact on the Fiscal Year 2024 **Federal Register** notices for the following FDA User Fee programs: Prescription Drug User Fee Amendments (PDUFA), Medical Device User Fee Amendments (MDUFA), Generic Drug User Fee Amendments (GDUFA), Biosimilar User Fee Amendments (BsUFA), Food Safety Modernization Act (FSMA), and Compounding Quality Act (CQA). The new physical address will be 3180 Rider Trail South, Earth City, MO 63045.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62080, Beltsville, MD 20705–4304, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this notice is to inform the public that the physical address for overnight packages for the U.S. Bank will change on October 6, 2023. The building's street address has changed from 1005 Convention Plaza, St. Louis, MO 63101, to 3180 Rider Trail South, Earth City, MO 63045. The last date to use the old address to deliver a check by courier, such as Federal Express or UPS, is October 5, 2023, and payers must use the new address for any packages beginning October 6, 2023, to prevent any disruption to the processing of their overnight package payments. Note that this new address is for courier delivery only.

If checks are to be sent by a courier that requires a street address, the courier can deliver the checks to:

- *For CQA and MDUFA:* U.S. Bank, ATTN: Government Lockbox 979033, 3180 Rider Trail South, Earth City, MO 63045.
- *For BsUFA, FSMA, and GDUFA:* U.S. Bank, ATTN: Government Lockbox 979108, 3180 Rider Trail South, Earth City, MO 63045.
- *For PDUFA:* U.S. Bank, ATTN: Government Lockbox 979107, 3180