DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.623]

Announcement of the Award of a Single-Source Expansion Supplement Grant to National Safe Place in Louisville, KY

AGENCY: Family and Youth Services Bureau (FYSB), ACYF, ACF, DHHS.

ACTION: Notice of the award.

SUMMARY: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB), Division of Adolescent Development and Support (DADS) announces the award of a single-source expansion supplement grant of $610,000 to Safe Place in Louisville, KY, to support costs associated with the expansion of the scope of approved activities under their award for the Runaway and Homeless Youth Training and Technical Assistance Center (RHYTTAC).

DATES: The award will support activities from August 1, 2014 through September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Christopher Holloway, Central Office Program Manager, Runaway and Homeless Youth Program, Division of Adolescent Development and Support, Family and Youth Services Bureau, 1250 Maryland Avenue SW., Suite 800, Washington, DC 20024; Telephone: 202–205–9560; Email: *Christopher.Holloway@acf.hhs.gov*

SUPPLEMENTARY INFORMATION: The expansion supplement award will allow National Safe Place to:

- Assist runaway and homeless youth (RHY) organizations with understanding and responding to the impact of toxic stress in the workplace through the creation of an annotated resource directory and distribution of other materials related to Toxic Stress Awareness and Response.
- Provide training and technical assistance (T & TA) to RHY grantees on enhancing sustainability and for the development of an RHY Sustainability Toolkit containing an extensive compilation of generalized information for sustainability of RHY organizations.
- Extend the Human Trafficking (HTR3) project to build upon and expand efforts in assisting programs with making the transition from understanding how to recognize and respect the victims of human trafficking to responding to the diverse needs of victims through the development of effective organizational practices and community collaborations.

Using evidence-based practices derived from the best available research, professional expertise, and input from youth and families, the Runaway and Homeless Youth Training and Technical Assistance Center (RHYTTAC), operated by the National Safe Place, serves as the centralized national resource for FYSB-funded RHY grantees. Training and technical assistance services are directed to assisting RHY grantees in engaging in continuous quality improvement of their services and to assist them in building their organizational capacity to effectively serve RHY with a focus on helping the nation's network of RHY service providers boost ''protective factors'' for their clients.

Statutory Authority: Runaway and Homeless Youth Act, 42 U.S.C. 5701 through 5752, amended by the Reconnecting Homeless Youth Act of 2008, Public Law 110–378.

Christopher Beach,

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

[FR Doc. 2014–27738 Filed 11–21–14; 8:45 am]

BILLING CODE 4184–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0329]

Fees for Human Drug Compounding Outsourcing Facilities Under the FD&C Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Quality and Security Act (DQSA). Entities that elect to register as outsourcing facilities must pay certain fees to be considered outsourcing facilities. This guidance describes the annual establishment fee, the reinspection fee, annual adjustments to fees required by law, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 guidance document. Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan Gil, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20903, 301–796–7900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' On November 27, 2013, President Obama signed the DQSA (Pub. L. 113–54) into law. The DQSA added a new section 503B to the FD&C Act (21 U.S.C. 353B) that created a category of entities called ''outsourcing facilities.'' Section 503B(d)(4) of the FD&C Act defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current