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.

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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

good manufacturing practice for drugs). This guidance describes in detail the fee types and amounts an entity must pay to satisfy the fee requirements of sections 503B and 744K of the FD&C Act to be deemed an outsourcing facility and maintain its status as an outsourcing facility, the adjustments to the fees required by law, how to qualify as a small business to obtain a reduction of the annual establishment fee, how and when to submit payment to FDA, the effect of failure to pay fees, and fee-related dispute resolution.

On April 1, 2014 (79 FR 18297), FDA announced the availability of the draft version of this guidance. The public comment period closed on June 2, 2014. One comment was received from the public, and FDA carefully considered that comment as it finalized the guidance. Some of the issues raised relate to matters that FDA intends to address in other policy documents and were not directly pertinent to the topics addressed in this guidance. During finalization of the guidance, FDA made both clarifying changes and minor editorial changes to the guidance and accompanying form. For example, FDA clarified that it intends to issue an invoice for reinspection fees within 14 calendar days of the close of the reinspection, and that the reinspection fee must be paid within 30 calendar days of the date of the invoice.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on fees associated with human drug compounding outsourcing facilities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons can submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments can be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0776.

IV. Electronic Access

Persons with access to the Internet can obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27692 Filed 11–21–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1428]

Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities; Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a revised draft guidance entitled ''Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The revised draft guidance addresses provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) added by the Drug Quality and Security Act (DQSA) and updates reporting instructions for drug compounders that choose to register as outsourcing facilities. Such compounders must report information on the drugs they have compounded in Structured Product Labeling (SPL) format using FDA's electronic submissions system. This revised draft guidance supersedes a draft guidance entitled ''Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comments on this revised draft guidance, submit either electronic or written comments on the revised draft guidance by January 23, 2015. Submit either electronic or written comments concerning the collection of information proposed in the revised draft guidance by January 23, 2015.

ADDRESSES: Submit written requests for single copies of the revised draft guidance document 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. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance.

Submit electronic comments on the revised draft 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: Lysette Deshields, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' In the **Federal Register** of December 4, 2013 (78 FR 72897), FDA issued a notice announcing the availability of an initial draft of this guidance entitled ''Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' That draft guidance addressed new provisions in the FD&C Act added by the DQSA and set forth an interim submission method for human drug compounders that choose to register as outsourcing facilities.

The comment period on the initial draft guidance ended on February 3, 2014. FDA received six comments on the draft. In response to received comments or on its own initiative, FDA made the following changes and updates in the revised draft guidance: (1) Modified the scope of the guidance to refer to product reports submitted in SPL format; (2) clarified the following elements required in a product report: ''Strength of the active ingredient per unit,'' ''package description,'' and