

expand the original scope of approved activities.

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 \$852,000 to the National Safe Place Network located in Louisville, KY, to support costs associated with the expansion of the scope of approved activities under its award for the Runaway and Homeless Youth Training and Technical Assistance Center (RHYTTAC).

DATES: The period of support under this supplement is September 30, 2015, through September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Christopher Holloway, Program Manager, Runaway and Homeless Youth Program, Division of Adolescent Development and Support, Family and Youth Services Bureau, 330 C Street SW., Washington, DC 20201. Telephone: 202-205-9560; Email: Christopher.Holloway@acf.hhs.gov.

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

- Provide Runaway and Homeless Youth (RHY) grantees with resources necessary to better understand and respond to human trafficking through the creation of a Community Awareness Toolkit and Youth Prevention Action Kit, which will enhance their sustainability to provide human trafficking related services;
- Provide a clear and responsive framework by which all grantees of Domestic Victims of Human Trafficking (DVHT) funding can access relevant

training and responsive technical assistance;

- Partner with a national leader in services to human trafficking victims/survivors to provide all RHY grantees with enhanced access to human trafficking information on assessments, referrals, applicable state laws and trafficking, including sex and labor categories;

- Provide stipends to grantees to assist them in meeting federal requirements to submit data under RHY-Homeless Management Information System (RHY-HMIS).

Using evidence-based practices derived from the best available research, professional expertise, and input from youth and families, RHYTTAC serves as a national resource for training and technical assistance directed to assisting RHY organizations in their engagement in continuous quality improvement of their services in building organizational capacity to effectively serve runaway and homeless youth. RHYTTAC's focus is to help 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, as most recently amended by the Reconnecting Homeless Youth Act of 2008, Public Law 110-378 on October 8, 2008.

Christopher Beach,
Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Independence Program.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Office of Planning Research and Evaluation (OPRE) is proposing an information collection activity as part of the Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Independence Program. The proposed information collection consists of site visits by staff from the Urban Institute and Chapin Hall at the University of Chicago to conduct formative evaluations of programs serving transition-age foster youth. The evaluations will include preliminary visits to discuss the evaluation process with program administrators. Then, the research team will conduct site visits to each program to speak with program leaders, partners and key stakeholders, front-line staff, and participants. These formative evaluations will determine programs' readiness for more rigorous evaluation in the future. The activities and products from this project will help ACF to fulfill their ongoing legislative mandate for program evaluation specified in the Foster Care Independence Act of 1999.

Respondents: Program leaders, partners and stakeholders, and front-line staff as well as young adults being served by the programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Discussion Guide for program leaders	48	24	4	1	96
Discussion Guide for program partners and stakeholders ..	80	40	2	1	80
Discussion Guide for program front-line staff	128	64	1	1	64
Focus Group Guide for program participants	200	100	1	2	200
Compilation and Submission of Administrative Data Files ..	24	12	2	12	288

Estimated Total Annual Burden Hours: 728.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the

information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C St SW.,

Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed

collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-E-2353]

Determination of Regulatory Review Period for Purposes of Patent Extension; CYRAMZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CYRAMZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by June 14, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 12, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2014-E-2353 for Determination of Regulatory Review Period for Purposes of Patent Extension; CYRAMZA.

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and