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. Written comments should be received within 60 days of this notice.

Proposed Project

All-Hazards Public Health Emergency Preparedness and Response Generic Data Collection—New—Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Data from agencies and individuals are needed to assist CDC in responding to and planning for domestic and international all-hazards public health emergencies. According to the glossary from the National Response Framework Resource Center, ''all-hazards'' is defined as ''describing an incident, natural or manmade, that warrants action to protect life, property, environment, and public health or safety, and to minimize disruptions of government, social, or economic activities.'' This generic IC requests the authority to collect a wide array of data from traditional and non-traditional public health sources to assist in this effort. This generic IC will enable CDC to collect data during public health emergencies (as the response is taking place) and after public health emergencies (as the recovery is taking place) to aid response and recovery efforts and to answer pre-determined research questions. These data may be used to inform our preparedness for subsequent emergencies that may potentially occur and also inform decisions made by CDC Director.

All-hazards public health emergencies are those events that are formally declared emergencies by Federal, State or local jurisdictions. Declarations can be made by the Secretary of the Department of Health and Human Services (DHHS) under Section 319 of the Public Health Service Act and at the state or local levels by the Governor, state public health officer, city or county council or mayor and the local public health officer respectively. During and after these emergencies, assistance may be needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe. Also, CDC may have to assist the State and local, tribal, and territorial levels of government with critical data collection to support immediate data needs for situational awareness. Situational Awareness has been defined as ''the perception of elements in the environment within a volume of time and space, the comprehension of their meaning, and the projection of their status in the near future.''

A three-year OMB approval is requested to allow CDC to collect data during and after emergencies. Data collected under this generic IC will use a variety of data collection methods. *Some of the methods include but are not limited to:* Personal interviews, telephone interviews, focus groups, institutional record reviews, medical record reviews, and paper or Internet questionnaires and other secure electronic data exchange. Each proposed data collection submitted under this generic IC will provide information pertaining to that particular public health emergency. Respondents will be advised of the nature of the activity, the length of time required for participation and that their participation is voluntary.

There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General Public	50,000	1	1	50,000
Total	50,000			

Dated: September 26, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–23883 Filed 10–2–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth and Families

AGENCY: Family and Youth Services Bureau, ACYF, ACF, HHS.

ACTION: Notice to Award Five Expansion Supplement Grants.

CFDA Number: 93.592.

Legislative Authority: The Family Violence Prevention and Services Act, 42 U.S.C. 10401 through 10421, as extended by the Department of Health and Human Services Appropriations Act, 2009, Public Law 111–8.

Total Amount of Awards: $400,000.

Project Period: September 30, 2009—September 29, 2010.

SUMMARY: This notice announces the award of expansion supplement grants to five grantees under the Family and Youth Services Bureau (FYSB)/Family Violence Prevention and Services Program. Expansion supplement awards are made to four technical assistance (TA) providers to support their capacity to enhance victim services by providing more extensive TA to local domestic violence programs and State domestic violence coalitions under the Open Doors to Safety: Capacity-Building Grant (Capacity-Building) project. The supplemental funds, coupled with the TA providers' expertise, will enable Open Doors Safety Capacity-Building project grantees to receive more training and site-specific consultation, so that they may build program capacity. The awards will also support State-level collaboration between domestic violence organizations and child welfare agencies. These combined efforts will strengthen the ability of domestic violence programs and their partners to better serve survivors who have diverse backgrounds, experiences, and abilities.

Technical assistance provider organizations	Amount of award	Location
Family Violence Prevention Fund	$175,000	San Francisco, CA.
Domestic Abuse Intervention Programs	50,000	Minneapolis, MN.
Hektoen Institute, LLC	50,000	Chicago, IL.
National Network to End Domestic Violence	100,000	Washington, DC.

A $25,000 expansion supplement grant is awarded to the Institute on Domestic Violence in the African American Community (IDVAAC), Minneapolis, MN, for the period of July 1, 2009 through September 30, 2009, to support development of conference materials, a scholarly publication on healing after domestic violence, and conference scholarships.

Contact for Further Information: Marylouise Kelley, Ph.D., Director, Family Violence Prevention and Services Program, 1250 Maryland Avenue, SW., Suite 8216, Washington, DC, 20024. Telephone: 202–104–5756 E-mail: *Marylouise.kelley@acf.hhs.gov.*

Dated: September 28, 2009.

Maiso L. Bryant,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. E9–23922 Filed 10–2–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0057]

Determination of Regulatory Review Period for Purposes of Patent Extension; EMEND FOR INJECTION

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EMEND FOR INJECTION 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 Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product EMEND FOR INJECTION (fosaprepitant meglumine). EMEND FOR INJECTION, in combination with other antiemetic agents, is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and for prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EMEND FOR INJECTION (U.S. Patent No. 5,691,336) from Merck & Co., Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EMEND FOR INJECTION represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EMEND FOR INJECTION is 4,473 days. Of this time, 3,810 days occurred during the testing phase of the regulatory review period, while 663 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 29, 1995. The applicant claims October 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 29, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 3, 2006. The applicant claims March 31, 2006, as the date the new drug application (NDA) for Emend for Injection (NDA 22–023) was initially submitted. However, FDA records indicate that NDA 22–023 was submitted on April 3, 2006.

3. *The date the application was approved*: January 25, 2008. FDA has verified the applicant's claim that NDA 22–023 was approved on January 25, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and