The intended use of the resulting data is for CDC to develop timely, relevant, clear, and engaging materials for the USVI regarding pregnancy prevention during the Zika outbreak.

CDC will use focus groups to collect the data. This methodology provides flexible in-depth exploration of the participants' perceptions and experience and yield descriptions in the participants' own words. Furthermore, the facilitator will have flexibility to pursue relevant and important issues as they arise during the discussion.

There is no cost to participants other than their time. The total estimated annualized burden hours are 144.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Women of reproductive age	Semi-structured qualitative focus group interview—females.	60	1	2	120
Men of reproductive age	Semi-structured qualitative focus group interview—males.	12	1	2	24
Total					144

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award of Five Single-Source Low-Cost Extension Supplement Grants Within the Office of Refugee Resettlement's Unaccompanied Children's Program

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

ACTION: Notice of award of five single-source low-cost extension supplement grants under the Unaccompanied Children's (UC) Program.

SUMMARY: ACF, ORR, announces the award of five single-source low-cost extension supplement grants for a total of $19,604,765 under the UC Program.

DATES: Low-cost extension supplement grants will support activities from October 1, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Director, Division of Children's Services, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: *DCSProgram@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following supplement grants will support the immediate need for additional capacity of shelter services to accommodate the increasing number of UC referred by the Department of Homeland Security (DHS) into ORR care. The increase in the UC population makes it necessary to expand the services to expedite the release of UC to designated sponsors. To prepare for an increase in referrals for shelter services, ORR will solicit proposals from one grantee to accommodate the referrals from DHS.

Grant No.	Grantee	Shelter current funding ending 9/30/16	Low-cost extension 10/1/16–12/31/16
Texas	International Educational Services, Inc.	$27,082,262	$6,926,653
Texas	International Educational Services, Inc.	15,451,597	6,701,163
Texas	International Educational Services, Inc.	6,180,591	1,582,169
Texas	International Educational Services, Inc.	8,269,202	2,057,311
Texas	International Educational Services, Inc.	9,148,344	2,337,469
Total		66,131,996	19,604,765

ORR is continuously monitoring its capacity to provide post-release services to UC in HHS custody.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing post-release services program through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility of safe and timely release of UC referred to its care by DHS. It also lets the U.S. Border Patrol continue its vital national security mission to prevent illegal migration and trafficking and protect the borders of the United States.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of UC from the Commissioner of the former Immigration and Naturalization Service to the Director of ORR in HHS.

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C. D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Christopher Beach,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration, Administration for Children and Families.

[FR Doc. 2016–29326 Filed 12–6–16; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3274]

Posting Adverse Event Report Data Associated With Conventional Foods, Dietary Supplements, and Cosmetics on the Internet; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of data extracted from adverse event reports from January 2004 to the present involving food (including food additives, color additives, and dietary supplements) and cosmetics regulated by our Center for Food Safety and Applied Nutrition (CFSAN). The data files are being made publicly available on FDA's Web site to improve transparency about adverse event reports involving CFSAN-regulated products and increase awareness about reporting these adverse events to FDA.

FOR FURTHER INFORMATION CONTACT: Lyle Canida, Center for Food Safety and Applied Nutrition (HFS–014), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1817.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of data extracted from the CFSAN Adverse Event Reporting System (CAERS) from adverse event reports involving food (including food additives, color additives, and dietary supplements) and cosmetics regulated by CFSAN that were submitted to FDA from January 2004 to the present. We will make these data files available on a quarterly basis on the FDA Web site at *http://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm.* Each posting will consist of adverse event report information entered in CAERS for the previous 3 months with a roughly one month delay. The data files are provided in ASCII format and include information on the following topics (if provided):

- Demographic (*e.g.,* age, gender) and administrative information regarding the adverse event;
- Date of event;
- Product role (suspect or concomitant);
- Reported brand/product name;
- Industry code/name;
- Reported symptom(s); and
- Outcome information.

What is CAERS?

The CAERS database collects reports submitted by consumers, health professionals, industry, and others about adverse health events and product complaints related to CFSAN-regulated products. It includes voluntary reports involving conventional foods, including food additives and color additives, and cosmetics, and both mandatory and voluntary reports with respect to adverse events involving dietary supplements. Reports are mandatory for dietary supplements used in the United States in the case of a serious adverse event that has resulted in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent one of those outcomes (*see* 21 U.S.C. 379aa–1). In such cases, dietary supplement manufacturers, packers, and distributors must notify FDA if they receive reports about serious adverse events associated with the use of the dietary supplement.

The goal of CAERS is to improve consumer protection by providing FDA with information from which we may be able to quickly identify situations in which the data provide a signal that a particular product may be harmful and should be investigated further.

However, we note that adverse event reports about a particular product and the total number of adverse event reports for a product in the CAERS database only reflect information reported and do not represent any conclusion by FDA about whether the product actually caused the adverse event(s). Because we constantly update CAERS with new information, the number of reports for a given product and the content of individual reports may change over time. Furthermore, even with respect to dietary supplements, for which reporting of serious adverse events is mandatory, adverse events associated with any product may be underreported. On the other hand, in some instances there may be duplicate reports in CAERS for the same adverse event because multiple people (such as an injured consumer and a health care provider who treated him or her) may have submitted reports. Questions and answers (Q&As) accompanying the data at our Web site explain the data limitations, as well as the reasons why we need complete reporting.

Why is CFSAN posting these data on the FDA Web site?

- We are making this information available for the purpose of improving transparency by providing the public, including researchers and health care professionals, with online access to information from adverse event reports about CFSAN-regulated products. This information has previously been available only through the process of specific requests under the Freedom of Information Act, 5 U.S.C. 552. In addition, we believe that posting these data may increase the number and completeness of the adverse event reports we receive. For the most part, FDA does not have pre-market authority over foods and cosmetics. As a result, identifying through post-market surveillance possible risks associated with these products is critical.

Where and when will data be posted?

- We will post CAERS data on a quarterly basis on the FDA Web site at *http://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm.* Each posting will include adverse event reports entered in CAERS for the previous 3 month period, with a roughly one month delay. So for example, if we post data files on the CAERS Web page in February, the information would consist of adverse event reports entered (or revised) in CAERS during the previous October thru December time period. Data files from the January thru March time period would be posted in the following May, and so on.

Dated: December 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29277 Filed 12–6–16; 8:45 am]

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