

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Part C Early Intervention Services Grant

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of Noncompetitive Replacement Award.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is issuing a non-competitive replacement award of Part C Early Intervention Services funds under Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006, to the Reading Hospital for services previously provided by the St. Joseph Medical Center in order to ensure continuity of critical HIV medical care and treatment services and to avoid a disruption of HIV clinical care to clients in the city of Reading, Pennsylvania, and all of Berks and Schuylkill Counties.

#### SUPPLEMENTARY INFORMATION:

*Grantee of Record:* St. Joseph Medical Center.

*Intended Recipient of the Award:* The Reading Hospital and Medical Center.

*Amount of the Award:* \$334,051.

**Authority:** Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51.

*CFDA Number:* 93.918.

*Project Period:* The period of support for the replacement award is from March 1, 2009, to March 31, 2010.

*Justification for the Exception to Competition:*

Critical funding for HIV medical care and treatment services to clients in the city of Reading, as well as Berks and Schuylkill counties in Pennsylvania, will be continued through a noncompetitive replacement award to the Reading Hospital. This is a temporary replacement award as the previous grant recipient serving this population notified HRSA that it could not continue providing services after February 27, 2009, (the original competitive project period was July 1, 2006, through June 30, 2009). The Reading Hospital is the best qualified grantee for this supplement for the following reasons: It is in the same locality as former grantee; it currently provides HIV medical care to many of the former grantee's clients; and it has the capability of providing comprehensive HIV/AIDS services to the city of Reading and nearby counties. The Reading Hospital is able to continue providing critical services to the service

population as originally supported under the award to St. Joseph's Medical Center while the service area is re-competed.

This supplement will cover the time period from March 1, 2009, through March 31, 2010. This service area will be included in the upcoming competition for the Part C HIV Early Intervention Services (EIS) competing application process for project periods starting April 1, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Maria C. Rios, via e-mail, [mrrios@hrsa.gov](mailto:mrrios@hrsa.gov), or via telephone, 301-443-0493.

Dated: April 17, 2009.

**Marcia K. Brand,**  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0187]

#### Small Entity Compliance Guide on Prior Notice of Imported Food; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for the final rule on prior notice of imported food. The final rule issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and it was published in the **Federal Register** of November 7, 2008. The SECG is entitled "What You Need to Know About Prior Notice of Imported Food Shipments—A Small Entity Compliance Guide," and it is intended to help all entities, especially small businesses, better understand the prior notice regulation.

**DATES:** Submit written or electronic comments on the SECG at any time.

**ADDRESSES:** Submit written requests for single copies of the SECG to the CFSAN Outreach and Information Center, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 1-877-366-3322, or email your request to [industry@fda.gov](mailto:industry@fda.gov).

Submit written comments concerning the SECG to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this SECG.

#### FOR FURTHER INFORMATION CONTACT:

Laura Draski, Office of Regulatory Affairs (HFC-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866-521-2297.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of November 7, 2008 (73 FR 66294), FDA issued the prior notice final rule implementing section 307 of the Bioterrorism Act. The prior notice final rule requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States.

FDA examined the economic implication of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that it would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG that explains the requirements of this regulation.

FDA is issuing this SECG as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). This SECG restates, in simplified format and language, FDA's current requirements for prior notice of imported food. As guidance, this document is not binding on either FDA or the public. FDA notes, however, that the regulation that serves as the basis for this guidance document establishes requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulations at 21 CFR part 1, subpart I, in addition to reading this SECG.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this SECG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets