fiscal year 2006 (October 1, 2005, through September 30, 2006).

**FOR FURTHER INFORMATION CONTACT:** David Forney, Chief, Vessel Sanitation Program, Division of Emergency and Environmental Health Services (EEHS), National Center for Environmental Health (NCEH), telephone (770) 488–7333 or e-mail *DForney@cdc.gov*.

**SUPPLEMENTARY INFORMATION:**

## Purpose and Background

The fee schedule for sanitation inspections of passenger cruise ships inspected under the Vessel Sanitation Program (VSP) was first published in the **Federal Register** on November 24, 1987 (52 FR 45019), and CDC began collecting fees on March 1, 1988. Since then, CDC has published the fee schedule annually. This notice announces fees effective October 1, 2005. The formula used to determine the fees is as follows:

*Average Cost Per Inspection = Total Cost of VSP ÷ Weight Number of Annual Inspection*

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The size/cost factor was established in the proposed fee schedule published in the **Federal Register** on July 17, 1987 (52 FR 27060), and revised in a schedule published in the **Federal Register** on November 28, 1989 (54 FR 48942). The revised size/cost factor is presented in Appendix A.

## Fees

The fee schedule (Appendix A) will be effective October 1, 2005, through September 30, 2006. The fee schedule, which became effective October 1, 2001, will remain the same in Fiscal year 2006. If travel expenses continue to increase, the fees may be adjusted before September 30, 2006, since travel constitutes a sizable portion of VSP's costs. If an adjustment is necessary, a notice will be published in the **Federal Register** 30 days before the effective date.

## Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of CDC's VSP.

Dated: August 30, 2005.

**Kenneth Rose,**

*Acting Director, Centers for Disease Control and Prevention (CDC), NCEH/ATSDR Office of Policy, Planning, and Evaluation.*

## Appendix A

SIZE/COST FACTOR

| Vessel size | GRT [1] | Average cost ($U.S.) per GRT |
|---|---|---|
| Extra Small | > 3,001 | 0.25 |
| Small | 3,001–15,000 | 0.50 |
| Medium | 15,001–30,000 | 1.00 |
| Large | 30,001–60,000 | 1.50 |
| Extra Large | > 60,000 | 2.00 |

FEE SCHEDULE OCTOBER 1, 2005–SEPTEMBER 30, 2006

| Vessel size | GRT [1] | Fee |
|---|---|---|
| Extra Small | > 3,001 | 1,150 |
| Small | 3,001–15,000 | 2,300 |
| Medium | 15,001–30,000 | 4,600 |
| Large | 30,001–60,000 | 6,900 |
| Extra Large | > 60,000 | 9,200 |

Inspections and reinspections involve the same procedure, require the same amount of time, and are therefore charged at the same rate.

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**BILLING CODE 4163–18–P**

[1] Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### WERC: A Consortium for Environmental Education and Technology Development, Annual Environmental Design Contest; Availability of Sole Source Competing Continuation Cooperative Agreement; Request for Application: RFA-FDA-CFSAN–2005–3; Catalog of Federal Domestic Assistance Number 93.103

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

**ACTION:** Notice.

## I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing its intent to accept and consider a single source competing continuation application for the award of a cooperative agreement to the Waste-Management Education and Research Consortium (WERC): A Consortium for Environmental Education and Technology Development to support the Annual Environmental Design Contest. FDA anticipates providing $106,000 (direct and indirect costs combined) in fiscal year 2005 in support of this research project. Subject to the availability of Federal funds and successful performance, 4 additional years of support up to $106,000 (direct and indirect costs combined) per year will be available. FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements,

FDA carefully considers the benefits such agreements will provide to the public. The cooperative agreement ensures FDA's continued participation and support in the Annual Environmental Design Contest. Through a mix of science and engineering, it creates new resources and stimulates new and timely solutions to real world environmental problems.

**II. Eligibility Information**

Competition is limited to WERC because it is a unique educational opportunity and is the only college level competition of its kind.

WERC, a Consortium for Environmental Education and Technology Development, a program of the College of Engineering at New Mexico State University, was established in 1990 under a cooperative agreement with the U.S. Department of Energy. Starting in 1991, WERC has conducted an Annual Environmental Design Contest which is a unique educational experience for students from throughout the world. The contest provides an opportunity for students to address real world environmental and food safety related problems, experience a team developed project, publish research papers, and network with experts and potential employers. The contest is open to any 2-year, 4-year, or graduate degree institution. A high school-level competition has been held concurrently with the university contest since 1997. Many of the tasks deal with waste disposal, ground water contamination, nuclear waste treatment, and similar subjects; however in 2001, a food safety track was added and the contest was broadened to include disciplines such as microbiology and chemical contaminants in foods. The FDA has supported this program since Fiscal Year 2000. This notice confirms FDA's intent to fund for another 5-year project period.

As of October 1, 2003, applicants are required to have a Dun and Bradstreet Number (DUNS) to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1–866–705–5711. You should identify yourself as a Federal grant applicant when you contact Dun and Bradstreet, Inc.

**III. Application and Submission**

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.gov* or *cpolit@oc.fda.gov*. This RFA can be viewed on Grants.gov under ''Grant Find.'' A copy of the complete RFA can also be viewed on the FDA/CFSAN website at *http://www.cfsan.fda.gov/list.html*. For issues regarding the programmatic aspects of this notice: Wendy Buckler, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1926, email: *wendy.buckler@fda.gov*.

Dated: September 1, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2001D–0044]**

### Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications.'' FDA is issuing this draft guidance to recommend an approach for determining whether a laboratory test may be performed by laboratories with a certificate of waiver under CLIA. This draft guidance replaces the previous draft guidance entitled ''Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver,'' March 1, 2001.

**DATES:** Submit written or electronic comments on this draft guidance by December 6, 2005. Submit written comments on the information collection provisions by November 7, 2005.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) for Waiver Applications'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the information collection provisions 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0443, ext. 144.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary) before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263(b)).

Laboratories that perform only tests that are ''simple'' and that have an ''insignificant risk of an erroneous result'' may obtain a certificate of waiver (42 U.S.C. 263a(c)(2)). The Secretary has delegated to FDA the authority to determine under CLIA whether particular tests (waived tests) are ''simple'' and have ''an insignificant risk of an erroneous result'' (April 27, 2004, 69 FR 22849). This draft guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application).

FDA previously issued a draft guidance entitled ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver'' on March 1, 2001. This new draft guidance replaces the previous draft guidance.

The changes compared to the previous draft guidance include the following: (1) Greater emphasis on scientifically-based flex studies and validation studies, linked to the hazard analysis for each device; (2) recognition that reference methods may not be