being specifically solicited or agreed to by prior discussion with the Grants Management Specialist.

PAGE LIMITATIONS AND CONTENT REQUIREMENTS (Page 4)

Disregard Page Limits under Research Plan, Sections a–d and adhere to the prescribed guidance in the Program Announcement.

C. SPECIFIC INSTRUCTIONS BUDGET INSTRUCTIONS (Page 11)

This Announcement does not use the modular budget format. Disregard instructions regarding the dollar limitations. PHS 398 Form Page 4 and Form Page 5 are required to be submitted by all applications regardless of the dollar amount requested.

Human Subject Research (Section 8.e, Pages 18–19)

Ensure that the application addresses the issue of Inclusion of Women and Ethnic and Racial Minorities in Research Involving Human Subjects. The application could be determined as non-responsive if this issue is not covered within the research plan.

SECTION II—SUBMITTING YOUR APPLICATION

Send the Application to the following address: Technical Information Management—PA# 04055 CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341–4146.

PLEASE DO NOT SEND THE APPLICATION TO THE NATIONAL INSTITUTES OF HEALTH

Disregard all instructions under Section A. INSTRUCTIONS (Page 31)

Disregard Sections B–D (Pages 34–35). Please refer to the Program Announcement Application Review Information (Section V) for the applicable CDC review process.

Disregard Section M, First Paragraph (Pages 53–54); Section N (Pages 54–55) and Section O (Pages 55–56); and all pages following Page 56.

Dated: December 10, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–31083 Filed 12–16–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0092]

Food and Cosmetic Security Guidances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document related to food security entitled ''Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance'' (food security guidance) and a guidance document related to cosmetics security entitled ''Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance'' (cosmetics security guidance). The food security preventive Measures Guidance'' is designed as an aid to operators of retail food stores and food service establishments (e.g., bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for homebound persons, mobile food carts, restaurants, and vending machine operators). It identifies the kinds of preventive measures that operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. The cosmetics security guidance is designed as an aid to operators of cosmetics establishments (e.g., firms that process, store, repack, relabel, distribute, or transport cosmetics or cosmetics ingredients). It identifies the kinds of preventive measures that operators may take to minimize the risk that cosmetics under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

DATES: You may submit written or electronic comments on the guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance,'' or ''Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance'' to John Kvenberg, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the documents 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: John Kvenberg, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2359, e-mail: *jkvenberg@cfsan.fda.gov* or Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS–400), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2300, e-mail: *dkraemer@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Operators of retail food store, food service, and cosmetics establishments are encouraged to review their current security procedures and controls in light of the potential for tampering or other malicious, criminal, or terrorist actions and make appropriate improvements.

FDA announced the availability of two guidance documents related to food security in the **Federal Register** of January 9, 2002 (67 FR 1224). They were entitled ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' and ''Importers and Filers: Food Security Preventive Measures Guidance.'' The agency solicited public comment, but indicated that the two guidance documents would be implemented immediately in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)). The two guidance documents were prompted by the tragedies of September 11, 2001, and the resulting scrutiny of, and interest in, food safety and security that followed.

A number of the comments on the two guidance documents urged FDA to issue guidance that was specifically tailored for the retail food store and food service sector. In response to these comments, the agency announced in the **Federal Register** of March 21, 2003 (68 FR 13932), the availability of a draft guidance document entitled ''Retail Food Store and Food Service Establishments: Food Security Preventive Measures Guidance.'' This draft guidance document identified the kinds of preventive measures that operators of retail food store and food service establishments (e.g., bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for homebound persons, mobile food carts, restaurants, and vending machine operators) can take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

In that same March 21, 2003, **Federal Register** notice, the agency also requested comment on whether the agency's package of food security guidance documents should be expanded to include coverage of cosmetics, in addition to foods. To facilitate such comments, the agency announced the availability of a draft guidance document entitled ''Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance'' (68 FR 13932). This draft guidance identified the kinds of preventive measures that operators of cosmetics establishments can take to minimize the risk that cosmetics under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It takes the operator through each segment of the cosmetics production system that is within their control, in order to minimize the risk of tampering or other malicious, criminal, or terrorist action at each segment. Implementation of these measures requires commitment from both management and employees to be successful and, therefore, both should participate in their development and review.

The agency solicited public comment on the draft guidance documents. FDA received three letters and three electronic responses, each containing one or more comments, from industry, consumer groups, and consumers in response to the draft guidance documents. The agency has reviewed and evaluated the comments and has determined that further modification of the guidance documents is unnecessary. The agency is therefore finalizing the draft guidances without revision.

The guidance documents are level 1 guidances issued consistent with FDA's good guidance practices regulation (§ 10.115) relating to the development, issuance, and use of guidance documents.

The guidance documents represent the agency's current thinking on appropriate measures that retail food store, food service, and cosmetics establishments may take to minimize the risk that foods or cosmetics under their control will be subjected to tampering or other malicious, criminal, or terrorist actions. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding these guidance documents. 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. The guidance documents and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of these guidance documents also are available on the Internet at *http://www.cfsan.fda.gov/guidance.html*. The guidance documents also can be viewed at: *http://www.fda.gov/ohrms/dockets*.

Dated: December 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–31048 Filed 12–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129.

Proposed Project: Children's Hospitals Graduate Medical Education Payment Program (CHGME PP) (OMB No. 0915–0247)—Revision

The CHGME PP was enacted by Pub. L. 106–129 to provide Federal support for graduate medical education (GME) to freestanding children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

Technical assistance workshops and consultation with applicant hospitals resulted in an opportunity for hospital representatives to raise issues and provide suggestions resulting in proposed revisions in the CHGME application forms and instructions.

Data is collected on the number of full-time equivalent residents in applicant children's hospitals' training programs to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will also be derived from a formula that requires the reporting of discharges, beds, and case mix index information from participating children's hospitals. Hospitals will be requested to submit such information in an annual application. Hospitals will also be requested to submit data on the number of full-time equivalent residents a second time during the Federal fiscal year to participate in the reconciliation payment process.

The estimated average annual reporting for this data collection is approximately 150 hours per hospital. The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
HRSA 99–1 (Initial)	60	1	60	24	1,440
HRSA 99–1 (Reconciliation)	60	1	60	8	480
HRSA 99–2 (Initial)	60	1	60	14	840
HRSA 99–2 (Reconciliation)	60	1	60	4	240