

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 To facilitate such comments, the agency announced the availability of a draft guidance document entitled "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" (68 FR 13932). This draft guidance identified the kinds of preventive measures that operators of cosmetics establishments can take to minimize the risk that cosmetics under their control will be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The agency solicited public comment on the draft guidance documents.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responses, each containing one or more comments, from industry, consumer groups, and consumers in response to the draft guidance documents.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.

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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