indicators used in health care facilities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

IV. Electronic Access

To receive a copy of ''Premarket Notification [510(k)] Submissions for Chemical Indicators'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1420) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*, or submit two paper copies of any mailed comments, except that individuals may submit one 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 Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–31384 Filed 12–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0562]

Compliance Policy Guide Sec.110.300—''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) Sec. 110.300 entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The CPG provides written guidance to FDA's staff on enforcement of section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which require, beginning on December 12, 2003, registration with FDA for all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance 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 document.

FOR FURTHER INFORMATION CONTACT:

Food for human consumption: Judith Gushee, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301–436–2417.

Food for animal consumption: Isabel Pocurull, Division of Animal Feeds, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 301–827–0175.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of CPG Sec.110.300 entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This guidance outlines for FDA staff the agency's policy on enforcement of section 305 of the Bioterrorism Act and its implementing regulation (68 FR 58894, October 10, 2003; to be codified at 21 CFR part 1, subpart H). The Bioterrorism Act and subpart H require that, beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States be registered with FDA.

FDA is issuing this document as level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). The CPG Sec. 110.300 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible. As noted, under section 305 of the Bioterrorism Act, the requirement that food facilities be registered is effective December 12, 2003, making it urgent that the agency explain how it intends to enforce this requirement.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. 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 and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: December 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–31376 Filed 12–17–03; 9:09 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 on (301)–443–1129.

Proposed Project: Health Center Expansion and Recruitment Survey—New

HRSA's Office of Rural Health Policy (ORHP) currently funds a number of Rural Health Research Centers in the United States, allocating funding through cooperative agreements. Authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241), ORHP conducts research and investigations to render assistance to appropriate public authorities in the areas of the health and well-being of rural populations in the United States. A major current initiative of HRSA is the expansion of Health Centers (HCs) receiving funding under section 330 of the PHS Act, which provides medical care to lower income Americans regardless of the ability to pay in rural and urban areas.

HCs are a key element of the nation's medical care safety net, and are scheduled to expand the scope of their operations in the near future. One of the issues affecting HC expansion is their ability to recruit adequate numbers of medical and administrative personnel to accomplish their mission, particularly in rural areas, where there have been persistent problems recruiting and retaining health care personnel. HRSA's Office of Rural Health Policy (ORHP) has funded a study in collaborative oversight with the Bureau of Primary Health Care (BPHC) and the Bureau of Health Professions (BHPr), to collect information from HCs on issues concerning the recruitment of various types of health professionals and administrative personnel.

This data collection effort is designed to assess the problems encountered by rural and remote HCs in their efforts to recruit needed personnel as well as the types of programs employed in recruitment efforts, and to compare these patterns with prevailing programs in urban HCs. This one-time survey will collect information on all HCs receiving section 330 grant funding in the United States. The survey includes 13 separate response items, and will collect information from HC administrators on health care professional staffing, recruitment trends and issues and needs among HCs throughout the nation. The data collected will improve HRSA's abilities in forecasting needs for personnel as HCs expand, planning recruitment programs and strategies, and implementing of local and national policy initiatives to meet the personnel demands of HCs so that access to health care is maximized.

The burden estimates are as follows:

Health center expansion and recruitment survey	Number of respondents	Number of responses per respondent	Total number of responses	Avg. burden/ hours per response	Total burden hours
Survey instruments	845	1	845	.25	211

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 11, 2003.

Tina M. Cheatham,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 03–31250 Filed 12–18–03; 8:45 am]

BILLING CODE 4165–15–P

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 on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Education Assistance Loan (HEAL) Program Regulations (OMB No. 0915–0108)—Revision

This clearance request is for a revision to the approval of the notification, reporting and recordkeeping requirements in the HEAL program to insure that the lenders, holders and schools participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under this OMB number,