manufacturer or distributor to review this notice of opportunity for a hearing to determine whether it covers any drug product that they manufacture or distribute. Such persons may request an opinion on the applicability of this notice to a specific drug product by writing to the Division of Prescription Drug Compliance and Surveillance (address above).

This notice of opportunity for a hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962 (Pub. L. 87–781), or for any other reason.

In accordance with section 505 of the act and parts 310 and 314 (21 CFR parts 310 and 314), an applicant and all other persons subject to this notice are hereby given an opportunity for a hearing to show why approval of the applications should not be withdrawn.

An applicant or any other person subject to this notice who decides to seek a hearing shall file: (1) On or before April 26, 1999, a written notice of appearance and request for hearing; and (2) on or before May 24, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in § 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in §§ 314.151 and 314.200 and in 21 CFR part 12.

The failure of an applicant or any other person subject to this notice to file a timely written notice of appearance and request for a hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug products.Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: March 3, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–7232 Filed 3–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on International Outreach and Training on Good Agricultural and Good Manufacturing Practices for Fresh Produce

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Workshop on International Outreach and Training on Good Agricultural and Good Manufacturing Practices for Fresh Produce. The topics to be discussed are developing a collaborative process for identifying training needs for foreign growers and producers who export fresh produce to the United States and identifying effective strategies to best meet those needs.

Date and Time: The meeting will be held on April 26 and 27, 1999, from 8:30 a.m. to 5:30 p.m., and on April 28, 1999, from 8:30 a.m. to 12 noon.

Location: The workshop will be held at the Inn and Conference Center, University of Maryland University College, University Blvd. at Adelphi Rd., College Park, MD, 301–985–7300.

Contact: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–2314, FAX 202–260–9653, e-mail ''cbrewer@oc.fda.gov''.

Registration: The meeting is open to the public. However, space is limited and preregistration is required. Send preregistration information (including name, title, firm name, address, telephone, and fax number), to Wendy Buckler, JIFSAN (HFS–6), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4153, FAX 202–260–1654, e-mail ''wbuckler@bangate.fda.gov''. Translation into Spanish will be available. Limited space will be available at no cost to groups interested in exhibiting outreach, education, and training materials on produce safety. However, all exhibitors must preregister with Ms. Buckler.

If you need special accommodations due to a disability, please contact Ms. Buckler at least 7 days in advance.

SUPPLEMENTARY INFORMATION: On October 2, 1997, the President announced the ''Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables'' (fresh produce safety initiative). As part of the fresh produce safety initiative, the President directed the Secretary of the Department of Health and Human Services (DHHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue within 1 year guidance on good agricultural practices and good manufacturing practices for fresh fruits and vegetables. FDA coordinated the effort for DHHS.

FDA announced the availability of the final good agricultural practices and good manufacturing practices guidance on October 29, 1998 (63 FR 58055), after receiving and considering comments on the draft guidance from producers, foreign governments, and trade associations both in writing and during two separate rounds of public meetings on successively more developed drafts of the guide. The final guide (the guide) details a broad approach on how to minimize microbial contamination of produce through the control of: Water, manure, worker health and hygiene,

field and facility sanitation, and transportation.

On February 24, 1998, USDA and FDA issued a progress report to the President on the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. The report summarized the progress USDA and FDA have made in providing good agricultural practices and good manufacturing practices guidance to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables. The report discussed, among other things, the agencies' plans for assisting domestic and foreign producers to improve those practices.

The report stated that education and outreach programs are essential to foster appropriate application of the guidance by the domestic and international fresh fruit and vegetable industry, and that such programs are pivotal to industry's understanding of the essential principles of the guidance, as well as the scientific and practical reasons for application of the guidance as everyday production and processing practice.

The FDA workshop will begin the process for determining how to develop an education and outreach program for growers and producers of fresh fruit and vegetables imported into the United States. Participants will have the opportunity to discuss the most effective approaches for education and training and to identify any science-based needs that will further the implementation of the guide. At the meeting, foreign and domestic scientific experts, extension professionals, and industry representatives will make presentations on the applications of the guide. Representatives from donor organizations (e.g., the InterAmerican Development Bank) will also address infrastructure improvements needed to enhance food safety. Although the meeting will not offer training, per se, participants will have the opportunity to share current educational information and industry strategies that can further enhance the microbiological safety of fresh fruits and vegetables and contribute to the development of an educational framework for users of the guide.

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7230 Filed 3–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–0282]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Blood Bank Inspection Checklist and Report and Supporting Regulations in 42 CFR 493.1269–493.1285; *Form No.:* HCFA–0282 (OMB# 0938–0170); *Use:* The Clinical Laboratory Improvement Amendments (CLIA) of 1988 requires the Department of Health and Human Services (HHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by HHS. The law provides for inspections on an announced or unannounced basis during regular hours of operation. All records and information having a bearing on whether the laboratory is being operated in accordance with the law can be requested by the surveyor. The HCFA–0282 is the Blood Bank Inspection Checklist and Report which is outlined in the CLIA of 1988.; *Frequency:* Biennially; *Affected Public:* Not-for-profit institutions, Business or other for-profit, Federal Government, and State, Local, and Tribal Government; *Number of Respondents:* 1,250; *Total Annual Responses:* 1,250; *Total Annual Hours:* 625.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 15, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–7292 Filed 3–24–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–0319, 2786, and R–0074]

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

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to