PRA submission combines OMB approval for PACE, WPP 0938–0844 with OMB approval for MSHO/MnDHO 0938–0899 and requests to administer the PHS to beneficiaries enrolled in MassHealth SCO as well as administer the PHS in year 2005. The main purpose of the PHS is to collect health status information that may be used to adjust Medicare payment to MSHO/MnDHO health plan organizations. It has been successfully pilot-tested to assess response rates and accuracy of responses under different distribution approaches. The pilot test enabled CMS to select an approach whereby PACE and Dual Eligible Demonstration enrollees will be sent surveys to fill out and can request assistance from family or professionals; *Frequency:* Annually; *Affected Public:* Individuals or Households and Not-for-profit institutions; *Number of Respondents:* 15,859; *Total Annual Responses:* 10,785; *Total Annual Hours:* 1,798.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *paperwork@cms.hhs.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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room: C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 10, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Strategic Affairs.

[FR Doc. 03–18059 Filed 7–16–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–588, CMS–1514, CMS–368/R–144]

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

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (CMS)), 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.

1. *Type of Information Collection Request:* Revision of a currently Approved collection; *Title of Information Collection:* Authorization agreement for electronic forms transfer; *Form No.:* CMS–0588 (OMB# 0938–0626); *Use:* The information is needed to allow providers to receive funds electronically in their bank accounts; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 1,250.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospital Request for Certification in the Medicare/Medicaid Program; *Form No.:* CMS–1514 (OMB# 0938–0380); *Use:* Section 1861 of the Social Security Act requires hospitals and critical access hospitals to be certified to participate in the Medicare/Medicaid program. These providers must complete the ''Hospital Request for Certification in the Medicare/Medicaid Program'' form in order to be certified or recertified; *Frequency: Annually; Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,300; *Total Annual Responses:* 2,000; *Total Annual Hours:* 500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate; *Form No.:* 0938–0582; *Use:* Section 1927 requires State Medicaid agencies to report to drug manufacturers and CMS on the drug utilization for their State and the amount of rebate to be paid by the manufacturer; *Frequency:* Quarterly; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 6,125.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 10, 2003.

Dawn Willinghan,

Acting Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–18060 Filed 7–16–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0195]

Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Necessity of the Use of Food Product Categories in Registration of Food Facilities.'' FDA has developed this guidance in response to section 305(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which states that FDA may require registrants to submit the general food categories of food manufactured, processed, packed, or held at the facility, if FDA determines ''through guidance'' that such information is necessary. This guidance contains FDA's finding that information about food categories is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

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 Office of Regulations and Policy (HFS–24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. 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 on the guidance to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Necessity of the Use of Food Product Categories in Registration of Food Facilities.'' FDA is issuing this guidance as a followup to the publication of its proposed regulation to implement the Bioterrorism Act's requirement that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with FDA by December 12, 2003. (See 68 FR 5378, February 3, 2003.) The final rule, which FDA plans to publish in the Federal Register by October 10, 2003, will implement section 305 of the Bioterrorism Act. Section 305 of the Bioterrorism Act requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations. Section 305 of the Bioterrorism Act also states that FDA may require registrants to submit the general food categories (as identified in § 170.3 (21 CFR 170.3)) of food manufactured, processed, packed, or held at the facility, if FDA determines through guidance that such information is necessary. This guidance contains FDA's finding that inclusion of food product categories in a facility's registration is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

FDA believes that information about a facility's food product categories is a key element to allow for rapid communications between FDA and facilities directly affected by an actual or potential bioterrorist attack or other food-related emergency. Information about the categories of food a facility handles will assist FDA in conducting investigations and surveillance operations in response to a food-related emergency. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. For example, if FDA receives information indicating that soft drinks could be affected by a bioterrorist incident or other food-related emergency, FDA would be able to alert soft drink manufacturers/processors,[1] packers, and holders about the incident. Additionally, the food categories in conjunction with the prior notification requirements that have been proposed for 21 CFR part 1, subpart I (68 FR 5428, February 3, 2003), would aid FDA in verifying that imported products are correctly identified by where and when they were produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice for a shipment of nuts purporting to have been produced at that facility, FDA can inspect the shipment for verification based on the discrepancy. FDA, therefore, proposed in § 1.232(e) of the proposed rule to include the food product categories listed in § 170.3 as a mandatory field on the registration form. (See 68 FR 5378 at 5419, February 3, 2003.) Since § 170.3 does not list all the categories of food that are manufactured/processed, packed, or held for consumption in the United States, FDA proposed to include additional food categories as an optional field on the registration form.

This guidance represents FDA's finding on the need for food product category information as part of the registration of food facilities under the Bioterrorism Act. Section 305 of the Bioterrorism Act directs FDA to require information about the food categories listed in § 170.3, if the agency determines ''through guidance'' that such information is a necessary component of registration. Because of Congress's explicit statutory authorization to establish a binding requirement based on a finding in guidance, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document's nonbinding effect. (See § 10.115(d) and (i) (21 CFR 10.115(d) and (i)).)

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited, and the agency's guidances also ordinarily include the following standard paragraph:

This guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Although this guidance has no binding effect, it contains a finding that serves as the predicate for a binding regulation that would impose a new requirement on industry. If the previsions of the proposed rule (68 FR 5378) regarding food categories are finalized as proposed, the final rule would require registrants to indicate in their registration which of the food

[1] In the proposed rule, FDA noted that the meanings of the terms ''manufacture'' and ''process'' overlap and proposed to define both activities together as ''manufacturing/processing.'' (See 68 FR 5378 at 5382, February 3, 2003.)

categories listed in § 170.3 they manufacture/process, pack, or hold. In that event, facilities would be unable to use an alternative approach to including those food categories in registration because no alternative approach would satisfy the requirements of the applicable statute and regulations. Therefore, FDA is not including the standard guidance paragraph in the guidance because it does not apply.

FDA is issuing this guidance document as a level 1 guidance. Consistent with FDA's GGP regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. FDA is under a strict statutory deadline in which to complete the final rule associated with this guidance. Moreover, the public has already had an opportunity to comment on the necessity of food product categories in the proposed rule.

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 paper copy of electronic comments to *http://www.fda.gov/dockets/ecomments* 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.cfsan.fda.gov/guidance.html*.

Dated: July 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–18087 Filed 7–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506 (c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: HRSA AIDS Education and Training Centers Evaluation Activities—NEW

The AIDS Education and Training Centers (AETC) Program, under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, supports a network of regional and cross-cutting national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of a national evaluation effort of AETC activities, one questionnaire and several record-keeping forms have been developed to capture information on AETC activities. The first form is the Participant Information Form and asks trainees for information on the individual's profession, type of clinical practice, and patient population. Recordkeeping forms include (1) The Program Record which records information such as topic, training time, number of people reached, and format per training activity, (2) the Clinical Consultation Form which collects information on consults with a provider regarding a specific patient, (3) the Group Clinical Consultation Form records information on the nature of the cases discussed and the session format during a site visit, and (4) the Agency Technical Assistance Form which collects information on activities to improve non-clinical aspects of care (*e.g.*, medical records, resource allocation). The information on the recordkeeping forms comprises a core data set that will be submitted to the HIV/AIDS Bureau (HAB) data contractor three times per year.

Each center will be required to report aggregate data from these forms on their activities to HRSA/HAB. This data collection will provide information on the number of training, consultation, and technical assistance activities by center, the number of health care providers receiving professional training or consultation, the time and effort expended on different types of training and consultation activities, the populations served by the AETC trainees, and the increase in capacity achieved through training and technical assistance activities. Collection of this information will allow HRSA/HAB to provide information on training activities, types of education and training provided to Ryan White CARE Act grantees, resource allocation, and capacity expansion.

Trainees will be asked to complete the Participant Information Form for each activity they complete. The estimated annual response burden to attendees of training programs is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Participant Information	75,000	2	150,000	0.2	30,000