

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>.

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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: 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