designated population or group to the activities of the Center.

CDC will require each ACE to form an ACE Community Committee. This group should comprise members of the ACE's defined community and adult and youth representatives of agencies and organizations serving that community. The inputs provided by an ACE Community Committee to the ACE include guidance, advice on ACE agendas and plans, expertise, contacts, essential information about the designated community as well as intangible benefits. Some ACE's may wish to form additional advisory groups, as needed, such as a policy board, a youth advisory board, or advisory committees for individual research projects. The decision to form these additional groups depends on the needs of the ACE and the community.

Center Partnerships

Each ACE is also expected to establish and maintain center partnerships with institutions such as state and local health, education justice departments, other university partners, other ACEs, Injury Control Research Centers (ICRCs), Prevention Research Centers, national youth violence prevention organizations, and CDC. Partnerships are intended to make the ACE's surveillance, research, training and mentoring, community mobilizing and dissemination activities relevant to its identified community. Partners can collaborate with the ACE in designing and conducting research and other ACE projects and in disseminating research findings, which are expected to help facilitate the translation of public health research and related activities to practice and policy.

Community-Based Participatory Research (CBPR)

Scientific inquiry conducted in communities in which community members, persons affected by condition or issue under study and other key stakeholders in the community's health have the opportunity to be full participants in each phase of the work (from conception—design—conduct—analysis—interpretation—conclusions—communication of results).

Definition Developed by Inter Agency Working Group for CBPR, Convened by NIEHS, NIH, August 2, 2002

According to the CARE–CDC Health Initiative, A Model for Global Participatory Research, in community-based participatory research, the definition of scientific rigor is broadened to encompass community participation in decisionmaking at every phase of the research process: defining the problem, setting goals, selecting methods, interpreting data, and recommending policy. Essential to this philosophical construct is the assurance of quality decision making throughout the research process. In the document Building Community Partnerships in Research, participatory research is described as the gold standard toward which all federally funded research should aspire. (5)(p7). [Building Community Partnerships in Research: Recommendations and Strategies. Executive Summary. Washington, DC: U.S. Dept of Health and Human Services; April 7, 1998.]

[FR Doc. 04–25667 Filed 11–19–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0494]

Guidance for Industry on Changes to an Approved New Drug Application or Abbreviated New Drug Application; Specifications—Use of Enforcement Discretion for Compendial Changes

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Changes to an Approved NDA or ANDA; Specifications—Use of Enforcement Discretion for Compendial Changes.'' This guidance informs new drug application (NDA) and abbreviated new drug application (ANDA) holders of FDA's plan to use enforcement discretion with regard to the regulation on changes to an approved application. This regulation describes the filing requirement that a relaxation of acceptance criteria or deletion of a test to comply with an official compendium must be reported in a changes-being-effected-in-30-days supplement (CBE–30). FDA does not intend to take enforcement action if manufacturers continue to submit such changes in their annual reports. The use of enforcement discretion will give the agency time to clarify that some of these types of postapproval changes can be submitted in an annual report, rather than in a CBE–30. The agency intends to clarify this issue in an upcoming revision to a guidance for industry.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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*. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David J. Cummings, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5187.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 8, 2004 (69 FR 18728), FDA published a final rule entitled ''Supplements and Other Changes to an Approved Application.'' In the same issue of the **Federal Register** (69 FR 18768), FDA announced the availability of the guidance for industry entitled ''Changes to an Approved NDA or ANDA'' (the changes guidance). Under § 314.70(c)(2)(iii) (21 CFR 314.70(c)(2)(iii)) of the final rule, the relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements must be submitted as a CBE–30 (see section VIII.C.1.e of the changes guidance).

FDA is issuing this guidance to explain that it is using enforcement discretion with regard to § 314.70(c)(2)(iii) to address concerns raised by stakeholders. FDA plans to clarify that some of these types of changes can be submitted in an annual report, instead of a CBE–30 supplement, in a revision of the guidance for industry entitled ''Changes to an Approved NDA or ANDA; Questions and Answers.''

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 (44 U.S.C. 3501–3520). The collection of information in

this guidance was approved under OMB Control No. 0910–0001 and 0910–0032.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on these topics. 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 statutes and regulations.

II. Comments

Interested persons may at any time submit to the Division of Dockets Management written or electronic comments on the guidance (see **ADDRESSES**). 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

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25748 Filed 11–19–04; 8:45 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

eriodically, the Health Resources and Services Administration (HRSA) publi tracts 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 Division of Independent Review Grant Reviewer Recruitment Form—New

HRSA's Division of Independent Review (DIR) is responsible for carrying out the independent review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical and complies with statutes, regulations and policies. The review of applications is performed by people knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the collection, selection and assignment of grant reviewers to independent review committees, HRSA will utilize a Web-based data collection form to gather critical reviewer information. The Grant Reviewer Recruitment Form will standardize pertinent categories of reviewer information, such as areas of expertise, occupations, work settings, reviewer experience, and allow maximum use of drop-down menus to simplify for the data collection process. All self-nominated reviewers will be channeled to the Grant Reviewer Recruitment Form. DIR anticipates a monthly volume of approximately 100 self-nominated responses. On a periodic basis, existing HRSA reviewers will be notified and directed to update their profile (via the Grant Reviewer Recruitment Form). HRSA maintains a pool of approximately 5,000 individuals that have previously served on HRSA independent review committees. DIR projects that approximately 3,700 individuals (or 75% of existing reviewers) would comply with instructions to update their profile on the Web-based Recruitment Form.

For existing HRSA reviewers, the amount of time required to complete the Recruitment Form will be abbreviated since HRSA will fill in the Form with previously collected personal information; existing reviewers will focus only on updating changes (*e.g.*, addresses, employer, expertise, occupation) to their profile. The estimate of burden for the HRSA Grant Reviewer Recruitment Form is as follows:

Type of respondent*	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden hours
New reviewer	1,200	1	1,200	45	900
Existing reviewer	3,700	1	3,700	30	1850
Total	4,900		4,900		2,750

*Includes two categories of grant reviewers: (1) new or self-nominated reviewers that have never served as a HRSA grant reviewer and (2) existing reviewers that have previously served on a HRSA independent review committee.

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

Dated: November 15, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–25751 Filed 11–19–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cooperative Agreement for the International AIDS Education and Training Center; CFDA 93.145

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of supplemental award.