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 all phases 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 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) 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 guidance change).

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

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:

1. 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)(ii) 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).
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.

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:

<table>
<thead>
<tr>
<th>Type of respondent*</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Total responses</th>
<th>Minutes per response</th>
<th>Total burden hours</th>
</tr>
</thead>
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<td>New reviewer</td>
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<td>1,200</td>
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<tr>
<td>Existing reviewer</td>
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<td>3,700</td>
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<tr>
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<td>4,900</td>
<td></td>
<td>2,750</td>
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</tbody>
</table>

*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.