Place: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

Status: This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-U.S. citizens, pre-approval is required (please contact Gwen Mustaf, 301–458–4500, *glm4@cdc.gov,* or Virginia Cain, *vcain@cdc.gov* at least 10 days in advance for requirements). All visitors are required to present a valid form of picture identification issued by a state, federal or international government. As required by the Federal Property Management Regulations, title 41, Code of Federal Regulation, subpart 101–20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters for Discussion: The agenda will include:

1. Welcome remarks by the Director, NCHS
2. An update on health insurance coverage data
3. A presentation on Statistical Policy Directive No. 1: ''Fundamental Responsibilities of Federal Statistical Agencies and Recognized Statistical Units''.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by January 8, 2015.

The agenda items are subject to change as priorities dictate.

Contact Person for More Information: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, telephone (301) 458–4500, fax (301) 458–4024.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–29963 Filed 12–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Grant Reviewer Recruitment Form.

OMB No.: NEW.

Description: The Administration for Children and Families's Children's Bureau (CB) is responsible for administering the review of eligible grant applications submitted in response to funding opportunity announcements issued by CB. CB ensures that the objective review process is independent, efficient, effective, economical, and complies with the applicable statutes, regulations, and policies. Applications are reviewed by subject experts knowledgeable in child welfare and related fields. Review findings are advisory to CB; CB is responsible for making award decisions.

This announcement is a request for approval of the proposed information collection system, the Reviewer Recruitment Module (RRM). CB will use a web-based data collection form and database to gather critical reviewer information in drop down menu format for data such as: degree, occupation, affiliations with organizations and institutions that serve special populations, and demographic information that may be voluntarily provided by a potential reviewer.

These data elements will help CB find and select expert grant reviewers for objective review committees. The web-based system will permit reviewers to access and update their information at will and as needed. The RRM will be accessible by the general public via *https://rrm.grantsolutions.gov/AgencyPortal/cb.aspx.*

Respondents: Generally, our reviewers are current or retired professionals with backgrounds in child welfare and related fields and in some instances current or former foster care parents or clients.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Reviewer recruitment module	500	1	.25	125

Estimated Total Annual Burden Hours: 125.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–29978 Filed 12–22–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 22, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0563. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice (OMB Control Number 0910–0563)—Extension

The guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP). Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements, or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance provides procedures that encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs (ORA) and center levels and for requesting review by the dispute resolution (DR) Panel.

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms prior to the issuance of Form FDA 483, the manufacturer can formally request DR and can use the formal two-tiered DR process described in the guidance.

Tier one of the formal DR process involves scientific or technical issues raised by a manufacturer to the ORA and center levels. If a manufacturer disagrees with the tier-one decision, tier-two of the formal DR process would then be available for appealing that decision to the DR panel. The written request for formal DR to the appropriate ORA unit should be made within 30 days of the completion of an inspection, and should include all supporting documentation and arguments for review, as described in this document. The written request for formal DR to the DR Panel should be made within 60 days of receipt of the tier-one decision and should include all supporting documentation and arguments, as described in the following paragraphs.

All requests for formal DR should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier-one DR or a request for tier-two DR;
- name and address of manufacturer inspected (as listed on FDA Form 483);
- date of inspection (as listed on Form FDA 483);
- date Form FDA 483 issued (from Form FDA 483);
- facility Establishment Identifier Number, if available (from Form FDA 483);
- FDA employee names and titles that conducted inspection (from Form FDA 483);
- office responsible for the inspection (*e.g.,* district office, as listed on Form FDA 483);
- application number if the inspection was a preapproval inspection;
- comprehensive statement of each issue to be resolved:
  - Identify the observation in dispute;
  - clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data;
  - state the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of Form FDA 483;
  - identify possible solutions; and
  - state expected outcome.
- Name, title, telephone and FAX number, and email address (as available) of manufacturer contact.

The guidance was initiated in response to industry's request for a formal DR process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained previously. The guidance also covers the following topics:

- The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.
- Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.
- Public availability of decisions reached during the DR process to promote consistent application and interpretation of drug quality-related regulations.

Description of Respondents: Pharmaceutical manufacturers of