

ESTIMATED ANNUALIZED BURDEN TABLE

Form	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Single Parent Caregiver Survey Instrument.	Single Parent Caregivers	1,000	1	20/60	333

John Teeter,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2011-21644 Filed 9-2-11; 8:45 am]

BILLING CODE 4150-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health; Cancellation

AGENCY: Office of Minority Health, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; Cancellation.

SUMMARY: A notice was published in the **Federal Register** on Tuesday, July 5, 2011, Vol. 76, No. 128, to announce that a meeting of the Advisory Committee on Minority Health (ACMH) was scheduled to be held on Monday, August 29, 2011 from 9 a.m. to 5 p.m., and Tuesday, August 30, 2011, from 9 a.m. to 1 p.m. This meeting has been cancelled in its entirety. The meeting was cancelled because of the weather projections that the Washington, DC metropolitan area would be affected by a significant hurricane. The meeting was cancelled to ensure the safety of the Committee members, Federal staff, and all other interested parties. Information about this meeting being rescheduled will be posted on the Committee's Web site, which can be accessed at <http://minorityhealth.hhs.gov>.

FOR FURTHER INFORMATION CONTACT: Ms. Monica A. Baltimore, Executive Director, ACMH; Suite 600 Tower Building, 1101 Wootton Parkway, Rockville, MD 20852. Telephone: (240) 453-2882; Fax: (240) 453-2883.

Dated: August 30, 2011.

Monica Baltimore,

Executive Director, Advisory Committee on Minority Health, Office of Minority Health, Office of the Assistant Secretary for Health.

[FR Doc. 2011-22659 Filed 9-2-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0447]

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 October 6, 2011.

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 e-mailed 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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, Juanmanuel.Vilela@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 the FDA Form 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