

## 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]

**BILLING CODE 4154-29-P**

## 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](mailto: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](mailto: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

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 FDA Form 483);
- Date the FDA Form 483 issued (from FDA Form 483);
- Facility Establishment Identifier (FEI) Number, if available (from FDA Form 483);
- FDA employee names and titles that conducted inspection (from FDA Form 483);
- Office responsible for the inspection (e.g., district office, as listed on the FDA Form 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 the FDA Form 483.

- Identify possible solutions.
- State expected outcome.
- Name, title, telephone and FAX number, and email address (as available) of manufacturer contact.

The guidance was part of the FDA initiative “Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,” which was announced in August 2002. The initiative focuses on FDA’s current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products. The Agency formed the Dispute Resolution Working Group comprising representatives from ORA, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine. The working group met weekly on issues related to the DR process and met with stakeholders in December 2002 to seek their input.

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.

In the **Federal Register** of June 20, 2011 (76 FR 35896), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The comment was not related to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for Tier-One Dispute Resolution .....	2	1	2	30	60
Requests for Tier-Two Dispute Resolution .....	1	1	1	8	8
<b>Total</b> .....					<b>68</b>

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

*Description of Respondents:* Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

*Burden Estimate:* Based on the number of requests for tier-one and tier-two dispute resolution received by FDA since the guidance published in January 2006, FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier-one DR and that there will be one appeal of these requests to the DR Panel (request for tier-two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR and approximately 8 hours to prepare and submit each request for a tier-two DR. Table 1 of this document provides

an estimate of the annual reporting burden for requests for tier-one and tier-two DRs.

Dated: August 31, 2011.

**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2011–22683 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–D–0530]

**Mobile Medical Applications Draft Guidance; Public Workshop; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Friday, August 12, 2011 (76 FR 50231). The document announced a public workshop entitled “Mobile