

*Proposed Project:* The Hospital Preparedness Program—Generic HPP and Future Collection Activities—New—OMB No. 0990—OS—Assistant Secretary for Preparedness and Response (ASPR).

*Abstract:* The Program Evaluation Section (PES), part of the Department of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Office of Preparedness and Emergency Operations (OPEO), Division of Preparedness Planning (DPP), in conjunction with the Hospital Preparedness Program (HPP) in the Division of National Healthcare Preparedness Programs, is seeking clearance by the Office of Management of Budget (OMB) for a Generic Data Collection Form to serve as the cornerstone of its effort to assess awardee performance under the HPP

Cooperative Agreement (CA) Program. Performance data are gathered from awardees as part of their Mid-Year and End-of-Year Progress Reports and other similar information collections (ICs) which have the same general purpose (Healthcare Coalitions, Capabilities and Budget Information), account for awardee spending and performance on all activities conducted in pursuit of achieving the HPP Grant goals.

Additionally, to reduce administrative burden on awardees, there is a need to develop reporting forms and templates that allow awardees and ASPR to more easily capture the data and other information already provided in the grant application at other times during the yearly grant cycle, and onsite visits by project and field officers (e.g. pre-populating some elements of the mid-year and end-of-year reporting). Such reporting will systematically capture

relevant information in a format that allows for easy access and use within a number of related grant business processes, including Grants management, Program and project management, and performance metrics and evaluation. A standardized program-specific application addendum will facilitate such data retrieval and decrease overall government administration costs.

This data collection effort is crucial to HPP's decision-making process regarding the continued existence, design and funding levels of this program. Results from these data analyses enable HPP to monitor healthcare emergency preparedness and progress towards national preparedness goals.

**Estimated Annualized Burden Table**

ESTIMATED ANNUAL BURDEN HOURS FOR THE GENERIC HPP AND FUTURE COLLECTION ACTIVITIES

| Data collection activity  | Number of respondents | Number of responses | Response time (hours) | Total annual burden hours (for all awardees) |
|---|-----------------------|---------------------|-----------------------|--|
| Generic and Future Program Data Information Collection(s) ..... | 62                    | 1                   | 58                    | 3,596  |
| Total .....   |                       |                     |                       | 3,596  |

**John Teeter,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990-new; 30-day notice]

**Agency Information Collection Request. 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this

collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB

Desk Officer; faxed to OMB at 202-395-5806.

*Proposed Project:* National Survey of Single Parent Caregivers—OMB No. 0990-NEW-OWH; HHS, Office on Women's Health.

*Abstract:* The National Survey of Single Parent Caregivers will measure the size, characteristics, and unmet needs of single parents providing care for an adult family member or friend. Single parent caregivers provide support services and financial assistance for two generations without the aid of a married partner. Survey results will be used to develop national estimates of the costs borne by single parent caregivers, their psychosocial burden, stress, and diminished social and leisure opportunities, and suggest policy options that mitigate the burden on single parent caregivers. The survey will be administered once under a one-year request, and will contact individuals using computer-assisted telephone interviewing (CATI) methods.

## 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]

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## 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](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