

results of national and State health care policies;

- Supply data for modeling the demand for health insurance; and
- Providing data on health plan choices, costs, and benefits that can be linked back to households' use of health care resources in the MEPS-HC for studies of the consumer health insurance selection process.

These data provide the basis for researchers to address important questions for employers and policymakers alike.

**Method of Collection**

The data will be collected using a combination of modes. The Census Bureau's first contact with employers will be made by telephone. This contact will provide information on the availability of health insurance from that employer and essential persons to contact. Based upon this information, Census will mail a questionnaire to the employer.

In order to assure high response rates, Census will follow-up with a second

mailing after an interval of approximately 30 working days, followed by a telephone call to collect data from those who have not responded by mail.

As part of this process, for larger respondents with high burdens, such as State employers and very large firms, we will, if needed, perform personal visits and do customized collection, such as, acceptance of data in computerized formats and use of special forms.

**Estimated Annual Respondent Burden**

Survey years	Annual number of respondents	Estimated time per respondent in hours	Estimated total annual burden hours	Estimated annual cost to the government
2004 .....	34,507	.6	19,708	\$8,800,000
2005 .....	34,507	.6	19,708	9,138,000
2006 .....	39,791	.6	23,550	10,660,000

**Request for Comments**

In accordance with the above cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the AHRQ, including whether the information will have practical utility; (b) the accuracy of the AHRQ's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: June 23, 2004.

**Carolyn M. Clancy,**

*Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Notice of Correction—Technical Review Meeting Date**

The original notice was published in the **Federal Register** on June 10, 2004 under Volume 69, Number 112, Pages 32558-32559 (<http://a257.g.akamaitech.net/7257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-13102.htm>). With this Notice, the Agency for Healthcare Research and Quality (AHRQ) is informing the public that the correct meeting date for the "AHRQ State and Regional Demonstrations in Health Information Technology" is July 7 and 8, 2004.

Dated: June 23, 2004.

**Carolyn M. Clancy,**

*Director, AHRQ.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004M-0203]

**Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and FDA's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**I. Background**

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were