

In Section VIII, strike the sentence "This Declaration has not previously been amended." and replace it with: "This is the first amendment to this Declaration. The Original Declaration was published in the **Federal Register** at 72 FR 4710."

All other provisions of the Original declaration remain in full force.

This amendment to the Declaration will be published in the **Federal Register** pursuant to section 319F-3(b)(4) of the Act.

DATES: This notice and the attached declaration are effective November 30, 2007.

FOR FURTHER INFORMATION CONTACT: RADM W. Craig Vanderwage, MD, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

Dated: November 21, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07-5884 Filed 11-29-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the renewal of the generic information collection project: "AHRQ Grants Reporting System (GRS)." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by December 31, 2007.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5036, Rockville,

MD 20850, or by e-mail at doris.lefkowitz@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

"AHRQ Grants Reporting System (GRS)"

AHRQ has identified the need to establish a systematic method for its grantees to report project progress and important preliminary findings for grants funded by the Agency. The proposed system will address the shortfalls in the current reporting process and establish a consistent and comprehensive grants reporting solution for AHRQ. Currently, AHRQ receives grants continuation applications on an annual basis from all grantees. The progress report, which represents a portion of the annual continuation application, is inadequate because it is too infrequent and does not necessarily capture the information that AHRQ requires to respond to internal and external inquiries. The reporting system will also provide a centralized repository of grants research information that can be used to support initiatives within the Agency's research plans for the future and to support activities such as performance monitoring, budgeting, knowledge transfer as well as strategic planning. AHRQ currently conducts quarterly conference calls with some grantees. The content, frequency, and focus of these calls vary. In some grant programs, the number of participants on these calls may be so large as to prohibit quarterly updates from all participants in order to avoid creating an extremely lengthy conference call and to allow the Agency to address other important issues during these calls. The GRS will support the timely collection of important information related to the life cycle of a grant. This information includes: Significant changes in project goals, methods, study design, sample or subjects, interventions, evaluation, dissemination, training, key personnel, key preliminary findings; significant problems and resolutions; publications and presentations; tools and products; and new collaborations/partnerships with AHRQ grantees or others conducting related research. Collecting

this information in a systematic manner will:

- Promote the transfer of critical information more frequently and efficiently which will enhance the Agency's ability to support research designed to improve the outcomes and quality of health care, reduce its costs, and broaden access to effective services.
- Increase the efficiency of the Agency in responding to ad-hoc information requests, Freedom of Information Act requests, and producing responses related to federally mandated programs and regulations.
- Establish a consistent approach throughout the Agency for information collection about grant progress and a systematic basis for oversight and for facilitating potential collaboration with or among grantees.
- Decrease the inconvenience and burden on grantees of unanticipated adhoc requests for information by the Agency in response to particular (one-time) internal and external requests for information.

This proposed information collection was previously published in the **Federal Register** on September 17th, 2007 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. This project was previously approved by OMB on November 10th, 2004. The OMB control number is 0935-0122 and will expire on November 30th, 2007.

Data Confidentiality Provisions

Confidential commercial information will be protected in accordance with 18 U.S.C. 1905. Information about Principal Investigators will be maintained in accordance with the Privacy Act, 5 U.S.C. 552a. Also, individuals and organizations will be assured of the confidentiality of their data under section 934(c) of the Healthcare Research and Quality Act of 1999. The submitted reports will be printed and included in the official file for each grant. All of these files will be retained according to existing agency policies and procedures and archived as required. The data will be collected using a Web based reporting interface developed specifically for the purpose of collecting information quarterly. To reduce burden and to the extent possible, these forms will be prepopulated with reoccurring information needed to specifically identify the institution, project, principal investigator, and other similar information.

EXHIBIT 1.—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Data entry into GRS	500	3	10/60	250
Total	500	na	na	250

EXHIBIT 2.—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Data entry into GRS	500	250	\$30.00	\$7,500
Total	500	250	na	7,500

*Based upon the average wages, "National Compensation Survey: Occupational Wages in the United States, May 2006," U.S. Department of Labor, Bureau of Labor Statistics.

This information collection will not impose a cost burden on the respondents beyond that associated with their time to provide the required data. There will be no additional costs for capital equipment, software, computer services, etc.

Estimated Annual Costs to the Federal Government

The annual cost to the government is \$100,000 for licensing, support and maintenance.

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 AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the 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 Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 26, 2007.

Carolyn M. Clancy,

Director.

[FR Doc. 07-5886 Filed 11-29-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0323]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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 December 31, 2007.

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: 202-395-6974, or e-mailed to baguilar@omb.eop.gov. All comments should be identified with the OMB control number 0910-0045. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

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.

Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—(OMB Control Number 0910-0045—Extension)

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). Under current¹ 21 CFR 207.20,

¹ This notice requests comments on the information collection in current part 207. In the **Federal Register** of August 29, 2006 (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally also require the electronic submission of all registration and most listing information. The August 29, 2006, proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the

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