

period of time. Written comments and suggestions regarding operation of the electronic docket are acceptable at any time. Cessation of the public docket is effective immediately.

**ADDRESSES:** Submit written comments on the management of the electronic docket to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** John F. Stigi, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597.

**SUPPLEMENTARY INFORMATION:**

Throughout its existence, the Center for Devices and Radiological Health (CDRH) has employed a number of outlets to communicate with regulated industry, the medical community, and interested consumers about its policies and operations. Although these modes of communication were generally regarded as effective, many persons expressed the desire for even broader access to CDRH-generated information to better assist them in complying with FDA regulatory requirements. In response, CDRH created two dockets to serve as readily accessible repositories of current and important materials. FDA announced the establishment of both dockets in the **Federal Register** of July 27, 1993 (58 FR 40150), and stated there would be a 1-year trial period for both information retrieval systems.

One docket, from which documents in "hard copy" form can be acquired, has been located at the Dockets Management Branch (address above). Interested persons were required to physically visit this facility in order to access the information.

CDRH also established an electronic docket as a means to further increase industry access to policy documents. This menu-driven system allows interested persons to access, read, print, and download documents using personal computers at their places of business.

Throughout the pilot year, CDRH has monitored the number of inquiries received through each of the two dockets. Approximately 100 document requests were made through the public ("hard copy") docket. In contrast, more than 17,000 inquiries were received through the electronic docket, and the number of system accesses continues to increase. During the period August through September 1994, slightly more than 5,800 requests were made. In addition to these utilization statistics, CDRH has taken note of articles,

editorials in trade publications, and correspondence that have commented favorably about the usefulness of the electronic docket in particular.

In view of the positive feedback on the electronic docket, as reflected by the comparatively large volume of inquiries, the agency believes there is sufficient justification for maintaining this public service. Persons interested in availing themselves of this information access system must have a video terminal or personal computer with communications software (VT emulation) and a modem that can operate at a baud rate of 1200, 2400, 4800, or 9600. For those persons who wish to transfer files from the electronic docket, the KERMIT file transfer protocol must be used. The telephone number to access the system is 1-800-252-1366 or 301-594-2741.

From the experience gained in operating the electronic docket, CDRH is contemplating a number of refinements to improve its information delivery capability, as well as the scope of material available for public access. These will include, for example, announcements of upcoming meetings of the agency's various medical device advisory panels. As other enhancements to the system are introduced, CDRH will inform potential users through CDRH newsletters, trade publications, public speeches, and other communication vehicles.

Effective immediately, FDA is terminating the public docket pilot program. Because of the marginal utilization of the public docket, CDRH believes that the administrative costs associated with its operation are no longer justified.

The actions announced in this notice do not affect the status of two other information access systems referred to in the **Federal Register** notice of July 7, 1993: (1) The CDRH "Flash FAX" system, from which virtually all documents formerly offered in the public docket are presently or shortly will be available; and (2) the premarket notification (510(k)) submission status reporting system.

To receive information or assistance regarding any of the systems described in this notice, contact the CDRH Division of Small Manufacturers Assistance at 1-800-638-2041 or 301-443-6597, or by FAX at 301-443-8818, or write to the contact person above.

Dated: January 13, 1995.

**D.B. Burlington,**

*Director, Center for Devices and Radiological Health.*

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## Health Care Financing Administration

### Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

Agency: Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96-511).

1. *Type of Information Collection:* New; *Type of Review Requested:* Regular submission; *Title of Information Collection:* Race and Ethnicity Survey; *Form No.:* HCFA-R-173; *Use:* This is a survey to improve the completeness of race and ethnicity information contained on the Medicare enrollment database; *Respondents:* Individuals or households; *Obligation to Respond:* Voluntary; *Number of Respondents:* 1,800,000; *Total Annual Responses:* 1,800,000; *Total Annual Hours Requested:* 60,000.

*Additional Information or Comments:* Call the Reports Clearance Office on (410) 966-5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 30, 1995.

**Kathleen B. Larson,**

*Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.*

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## National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.