

### III. Electronic Access

To receive "Guidance for Industry and FDA; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices" by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1216) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

### IV. Paperwork Reduction Act of 1995

This notice and the guidance entitled "Guidance for Industry and FDA; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices" contain a proposed collection of information that requires clearance by OMB under the Paperwork Reduction Act of 1995. In a document published elsewhere in this issue of the **Federal Register**, FDA is announcing that this proposed collection of information has been submitted to OMB for emergency processing. The notice also solicits comments concerning the proposed collection of information.

FDA will publish a separate notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions contained in this notice and the guidance. An agency may not

conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

### V. Comments

You may submit written or electronic comments regarding this guidance to the Division of Dockets Management (see **ADDRESSES**). You should submit two copies of a written comment or one copy of an electronic comment. Individuals may submit one copy of a written comment. You should identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments are available in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 27, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506 (c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden 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 through the use of automated collection techniques

or other forms of information technology.

#### Proposed Project: Health Center Expansion and Recruitment Survey—New

HRSA's Office of Rural Health Policy (ORHP) currently funds a number of Rural Health Research Centers in the United States, allocating funding through cooperative agreements. Authorized by section 301 of the Public Health Service Act (42 U.S.C. 241), ORHP conducts research and investigations to render assistance to appropriate public authorities in the areas of the health and well-being of rural populations in the United States. A major current initiative of HRSA is the expansion of Health Centers (HCs), which provide medical care to lower income Americans on the basis of ability to pay in rural and urban areas.

HCs are a key element of the nation's medical care safety net, and are scheduled to expand the scope of their operations in the near future. One of the issues affecting HC expansion is their ability to recruit adequate numbers of medical and administrative personnel to accomplish their mission, particularly in rural areas, where there have been persistent problems recruiting and retaining health care personnel. HRSA's Office of Rural Health Policy (ORHP) has funded a study in collaborative oversight with the Bureau of Primary Health Care (BPHC) and the Bureau of Health Professions (BHP), to collect information from HCs on issues concerning the recruitment of various types of health professionals and administrative personnel.

This data collection effort is designed to assess the problems encountered by rural and remote HCs in their efforts to recruit needed personnel as well as the types of programs employed in recruitment efforts, and to compare these patterns with prevailing programs in urban HCs. This one-time survey will collect information on all HCs in the United States. The survey includes 13 separate response items, and will collect information from HC administrators on health care professional staffing, recruitment trends, and issues and needs among HCs throughout the nation. The data collected will improve HRSA's abilities in forecasting needs for personnel as HCs expand, planning recruitment programs and strategies, and implementation of local and national policy initiatives to meet the personnel demands of HCs so that access to health care is maximized.

*The burden estimates are as follows:*