

other way provides equivalent assurances of safety and effectiveness.

**II. Significance of Guidance**

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on vascular and neurovascular embolization devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

**III. Paperwork Reduction Act of 1995**

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing 510(k) submissions (21 CFR part 807, subpart E, OMB control number 0910-0120). The labeling provisions addressed in the guidance document have been approved by OMB under the PRA, OMB control number 0910-0485.

**IV. Comments**

You may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. You may submit a single copy of an electronic comment (see **ADDRESSES**). Submit two copies of any mailed comments, but individuals may submit one copy. You should identify your comment with the docket number found in brackets in the heading of this document. You may see any comments FDA receives in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

To receive a copy of the draft guidance by fax machine, call the CDRH Facts-On-Demand system at 800-899-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 (1234) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so using the Internet.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** notices, 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>.

Dated: February 11, 2004.

**Beverly Chernaik Rothstein,**

*Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the

Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

*Proposed Project:* The National Health Service Corps (NHSC) Scholarship Program Deferment Request Forms and Associated Reporting Requirements (OMB No. 0915-0179)—Extension.

The National Health Service Corps (NHSC) Scholarship Program was established to assure an adequate supply of trained primary care health professionals to the neediest communities in the Health Professional Shortage Areas (HPSAs) of the United States. Under the program, allopathic physicians, osteopathic physicians, dentists, nurse practitioners, nurse midwives, physician assistants, and, if needed by the NHSC program, students of other health professionals are offered the opportunity to enter into a contractual agreement with the Secretary under which the Public Health Service agrees to pay the total school tuition, required fees and a stipend for living expenses. In exchange, the scholarship recipient agrees to provide full-time clinical services at a site in a federally designated HPSA.

Once the scholars have met their academic requirements, the law requires that individuals receiving a degree from a school of medicine, osteopathic medicine or dentistry be allowed to defer their service obligation for a maximum of 3 years to complete approved internship, residency or other advanced clinical training. The Deferment Request Form provides the information necessary for considering the period and type of training for which deferment of the service obligation will be approved.

The estimated response burden is as follows:

| Form                                | Number of respondents | Responses per respondent | Hours per response | Total hour burden |
|-------------------------------------|-----------------------|--------------------------|--------------------|-------------------|
| Deferment Request Forms .....       | 600                   | 1                        | 1                  | 600               |
| Letters of Intent and Request ..... | 100                   | 1                        | 1                  | 100               |
| <b>Total .....</b>                  | <b>700</b>            | <b>.....</b>             | <b>.....</b>       | <b>700</b>        |

Written comments and recommendations concerning the

proposed information collection should be sent within 30 days of this notice to:

Desk Officer, Health Resources and Services Administration, Human

Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 18, 2004.

**Tina M. Cheatham,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 04-4035 Filed 2-24-04; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork

Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: The National Health Service Corps (NHSC) Scholarship Program In-School Worksheets (OMB No. 0915-0250)—Extension**

The National Health Service Corps (NHSC) Scholarship Program was established to help alleviate the geographical and specialty maldistribution of physicians and other health practitioners in the United States. Under this program, health professional students are offered scholarships in return for services in a federally-designated Health Professional Shortage Area (HPSA). If awarded an NHSC Scholarship, the Program requires the schools and the awardees to review and complete data collection worksheets for

each year that the student is a NHSC Scholar.

The *Data Sheet* requests that the NHSC Scholar review the form for the accuracy of information such as, social security number, contact information, current curriculum, and date of graduation. If the information is inaccurate, the scholar makes the necessary changes directly on the form. If the inaccurate information pertains to the curriculum or date of graduation, the scholar will make changes directly on the form and include written notification from the school.

The *Verification Sheet* is sent to the school along with a list of the NHSC scholars that are enrolled for the current academic year. The schools verify and/or correct the enrollment status of each of the scholars on the list.

The *Contact Sheet* requests contact information for pertinent school officials. This information is used by the NHSC Scholarship Program for future contacts with the schools. The estimated burden is as follows:

| Form name                | Number of respondents | Responses per respondent | Hours per response (in minutes) | Total burden hours |
|--------------------------|-----------------------|--------------------------|---------------------------------|--------------------|
| Scholar Data Sheet ..... | 800                   | 1                        | 10                              | 134                |
| Verification Sheet ..... | 300                   | 1                        | 10                              | 50                 |
| Contact Sheet .....      | 550                   | 1                        | 10                              | 92                 |
| Total .....              | 1,350                 | .....                    | .....                           | 276                |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 17, 2004.

**Tina M. Cheatham,**

*Director, Division of Policy Review and Coordination.*

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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, Public Law 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 a 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: The Organ Procurement and Transplantation Network—New**

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain record keeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. OMB requires review and approval of certain information collection requirements associated with the Final Rule that were not included in previous clearance requests. This is a request for approval of record keeping and reporting requirements associated with the processes for filing appeals in the case where applicants are rejected for membership or designation. To date, no appeals have been filed, and any forthcoming burden requirements for this process will be minimal. In the event of an appeal, the estimate of burden for this process consists of preparing a letter requesting