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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2004N-0395]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on an application for participation in the Medical Device Fellowship Program (MDFP). Elsewhere in this issue of the **Federal Register** FDA published a notice announcing the Office of Management and Budget's (OMB's) approval of this collection of information (OMB control number 0910-0551). Since this was an emergency approval that expires on February 28, 2005, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register.]*

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity

of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the Medical Device Fellowship Program (OMB Control Number 0910-0551)—Extension

Collecting applications for the MDFP will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA Form 3608	100	1	100	1	100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on the number of inquiries that have been received about the program and requests for application forms over the past year. We anticipate the number of interested individuals and universities, and subsequent number of applications, to increase as we continue to develop an outreach program and an alumni base.

In addition, we would expect applicants who are not selected for their preferred term of employment to reapply at a later date. For these reasons we would expect that the number of applications submitted in the second and

third years would increase substantially. During the first year, we expect to receive 100 applications. We believe that we will receive approximately 100 applications the second year and 100 applications the third year. FDA believes

it will take individuals 1 hour to complete the application. This is based on similar applications submitted to FDA.

Dated: 9/9/04

September 9, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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