

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2004N-0275]

**Agency Emergency Processing Under Office of Management and Budget
Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is for an application form for participation in the medical device fellowship program (MDFP). FDA will use the information collected to identify qualified health professionals and students to provide expertise in the Center for Drugs and and Radiological Health (CDRH) regulatory process for medical devices.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the **Federal Register**]*. FDA is requesting approval of this emergency processing by *[insert date 45 days after date of publication in the **Federal Register**]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received,

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OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–205–6974.

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: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. This information is needed immediately so that the agency can effectively recruit outside expertise to aid in the review of medical device marketing applications. Outside experts are needed to fill gaps in current expertise and provide a flexible workforce capable of addressing changing medical device technology. A formal application and collection process would enable FDA to collect the necessary information from applicants in a timely and consistent manner. The application form will provide clear directions for applicants on what information to submit and a user-friendly format for submitting it, as well as reduce administrative costs for CDRH in collecting the information. The information to be collected is not available elsewhere.

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; Form FDA 3608

Collecting applications for the MDFP will allow 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
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 we've 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: 7-2-04
July 2, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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