TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Product | No. of Respondents | Annual Frequency per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Shell eggs | 10 | 1 | 10 | 0.25 | 3 |
| Dairy | 100 | 1 | 100 | 0.25 | 25 |
| Game meat and meat products | 5 | 1 | 5 | 0.25 | 1 |
| Animal casings | 5 | 1 | 5 | 0.25 | 1 |
| Gelatin | 3 | 1 | 3 | 0.25 | 1 |
| Collagen | 3 | 1 | 3 | 0.25 | 1 |
| Total | | | | | 32 |

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN (DISCLOSURE)[1]

| Product | No. of Respondents | Annual Frequency per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Trade association | 15 | 1 | 15 | 8 | 120 |
| State | 50 | 1 | 50 | 8 | 400 |
| Total | | | | | 520 |

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

It is estimated that the annual reporting burden would be no more than 32 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. The number of respondents is a rough estimate based on volume of exports and responses received to date. No record retention is required. Therefore, the proposed annual burden for this information collection is 32 hours.

Dated: July 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–15661 Filed 7–8–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0132]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

**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 review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 9, 2004.

**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, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Premarket Approval of Medical Devices—21 CFR Part 814 (OMB Control Number 0910–0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either preamendments devices that have been classified into class III, postamendments devices which are not substantially equivalent to a preamendments device, or transitional devices. Class III devices are devices such as implants, life-sustaining or life-supporting devices, or devices which otherwise present a potentially unreasonable risk of illness or injury, or are of substantial importance in preventing impairment of human health. Most premarket approval application (PMAs) are for postamendments class III devices.

Under section 515 of the act, an application must contain several pieces of information including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties and of the principle or principles of operation of such a device and should also include a full description of the methods used in, and the facilities and controls used for the

manufacture and processing of the device; and labeling specimens.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a class III medical device and the criteria FDA employs in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulation's purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval) medical devices. The regulations contained in part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the disapproval of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105–115) was enacted on November 21, 1997, to implement revisions to the act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several provisions of FDAMA affect the PMA process, such as section 515(d)(6) of the act. This section of the act provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, in the past 3 years FDA has done the following: Made changes to the PMA program based on comments received, complied with changes to the program mandated by FDAMA, and worked towards completion of its PMA reinvention efforts.

Respondents to this information collection are persons filing a PMA application or a PMA supplement with FDA for approval of certain class III medical devices. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include entities meeting the definition of manufacturers such as manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments). Additionally, hospitals that reuse single use devices (SUDs) are also included in the definition of manufacturers. It is expected that FDA will receive four PMA applications from hospitals that remanufacture SUDs annually. This figure has been included intable 1 of this document, as part of the reporting burden in § 814.15.

In the **Federal Register** of April 5, 2004 (69 FR 17689), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The total estimated reporting and recordkeeping burden for this information collection is 113,464 hours. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 814.15, 814.20, and 814.37 | 64 | 1 | 64 | 837 | 53,568 |
| 814.39(f) | 581 | 1 | 581 | 66 | 33,346 |
| 814.82 | 45 | 1 | 45 | 135 | 6,075 |
| 814.84 | 45 | 1 | 45 | 10 | 450 |
| Section 201 (FDAMA) | 10 | 1 | 10 | 10 | 100 |
| Section 202 (FDAMA) | 15 | 1 | 15 | 10 | 150 |
| Section 205 (FDAMA) | 8 | 1 | 8 | 50 | 400 |
| Section 208 (FDAMA) | 26 | 1 | 26 | 30 | 780 |
| Section 209 (FDAMA) | 8 | 1 | 8 | 40 | 320 |
| Total | | | | | 95,189 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 814.82(a)(5) and (a)(6) | 1,075 | 1 | 1,075 | 17 | 18,275 |
| Total | | | | | 18,275 |

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

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of 64 PMA original applications and 581 PMA supplements, using FY 1998 through 2002 data.

The burden data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows:

- Clinical investigations: 67 percent of total burden estimate;
- Submission of additional data or information to FDA during a PMA review: 12 percent;
- Additional device development cost (e.g., testing): 10 percent; and
- PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data: 11 percent.

**Paperwork Burden Estimate**

The burden estimates were derived by consultation with FDA and industry personnel. FDA's estimates are based on actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals.

**Reporting/Disclosure**

The reporting burden can be broken out by certain sections of the PMA regulation as follows:

- § 814.15—Research conducted outside the United States
- § 814.20—Application
- § 814.3—PMA amendments and resubmitted PMAs

The majority of the burden—53,568 burden hours—is due to the previously listed three requirements. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 64 manufacturers (including hospital remanufacturers of single use devices) will be affected by these requirements based on actual average FDA receipt of new PMA applications in FY 1998 through 2002. FDA's estimate of the hours per response (837) was derived through FDA's experience and consultationwith industry and trade associations. Included in these three requirements are the conduct of laboratory and clinical trails as well as the analysis, review, and physical preparation of the PMA application. In addition, FDA has based its estimate on the results of an earlier study that these requirements account for the bulk of the burden identified by manufacturers.

- § 814.39(f)—PMA supplements: 33,346 burden hours

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 10 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 33,346 hours of burden are needed to complete the requirements for regular PMA supplements.

- § 814.82—Postapproval requirements: 6,075 burden hours

Postapproval requirements concern approved PMAs that were not reclassified and require a periodic report. The range of PMAs that fit this category averaged approximately 45 per year (70 percent of the 64 periodic submissions). Most approved PMAs have been subject to some postapproval study requirement. Approximately half of the average submitted PMAs (32) require associated postapproval studies (i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information) that is labor-intensive to compile and complete, and the other PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by § 814.82 require 6,075 hours (135 hours per respondent).

- § 814.84—Reports: 450 burden hours

Postapproval requirements described in § 814.82 require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on a periodic basis. As stated previously in this document, the range of PMAs fitting this category averaged approximately 45 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by § 814.84 will take 450 hours.

**Statutory Burden**

The total hours for statutory burden is 1,750. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was derived to forecast future expectations with regard to this statutory data.

**Recordkeeping**

The recordkeeping burden in this section involves the maintenance of records used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records would be required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved and 75 percent of those have original clinical trial data. Therefore, approximately 45 PMAs a year (64 annual submissions x 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of active PMA applications must maintain these records. PMAs have been required since 1976, and there are 1,075 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 1,075 holders of approved

original PMAs, therefore, is 18,275 hours (1,075 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Dated: July 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–15662 Filed 7–8–04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[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 August 9, 2004. FDA is requesting approval of this emergency processing by August 23, 2004.

**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, 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 BURDEN[1]

| 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 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.