the MERS–TM to track internal events will be recruited to participate. These facilities will be asked to fill in the textual description of the blood-product related adverse event and to transfer the two outcome codes from the MERS–TM concerning problems with blood products to two additional data fields in the electronic format that will be dedicated to collecting this coded information. FDA will compare the information obtained in this reporting system with that obtained under existing mandatory and voluntary systems that are in place for transfusion-related fatalities, product deviations, and clinical adverse events. FDA will consider the information that is voluntarily reported under this pilot program to design a system that will assist FDA in gathering the most useful data, in the least burdensome manner, for its regulation (including packaging and labeling provisions) of establishments and products used in transfusion medicine.

Participation in this pilot will be voluntary and will initially include 25 hospitals that will respond to the medical device questions. At the same time, an initial nine blood establishments and transfusion services sites, which currently use the MERS–TM, will be recruited to participate. It is anticipated that during this pilot the number of participants will increase to approximately 250 facilities reporting medical device problems and the number of blood establishments and transfusion-services sites is anticipated to increase to 30. The electronic version will take approximately 45 minutes, or less, to complete. For the blood centers that are participating, the burden of participation will be approximately 15 minutes.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|
| Medical devices: 83 | 15 | 1,245 | .75 | 934 |
| Blood transfusions: 10 | 150 | 1,500 | .25 | 375 |

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

The number of respondents for medical devices was determined by the average number of respondents given that 25 facilities will be enrolled in the first year, up to 100 the second year, and up to 250 the third year. Eighty three is the average of the final complement of 250 facilities. The annual frequency of response is based on FDA's experience with its mandatory and voluntary reporting systems.

The number of respondents for blood transfusions was determined by the average number of respondents given that a total of 30 blood establishments will be enrolled at the end of 3 years. The annual frequency of response was based on the information that the American Red Cross submits about 15 reports per establishment per year. The MERS–TM will yield about a tenfold higher than the American Red Cross rate since it will include close-calls as well as actual adverse events.

Dated: February 2, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01–3321 Filed 2–7–01; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0050]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Classification/Reclassification; Restricted Devices: Premarket Approval of Medical Devices

**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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for premarket approval of medical devices.

**DATES:** Submit written or electronic comments on the collection of information by April 9, 2001.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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 Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (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: (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.

**Premarket Approval of Medical Devices—21 CFR Part 814 (OMB Control No. 0910–0231)—Extension**

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(e)) 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 for which are of substantial importance in preventing impairment of human health. Most premarket approval applications (PMA's) 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 PMA's. The regulation's purpose is to establish an efficient and thorough procedure for FDA's review of PMA's and supplements to PMA's for certain class III (premarket approval) medical devices. The regulations contained in part 814 facilitate the approval of PMA's and supplements to PMA's 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 PMA's and supplements to PMA's for devices that have not been show 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 this act affect the PMA process, such as section 515(d)(6) of the act. This section 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, FDA has in the past 3 years made changes to the PMA program based on comments received, has complied with changes to the program mandated by FDAMA and has 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 re-use single use devices (SUD's) are also included in the definition of manufacturers. For the next 3 years, it is expected that FDA will receive four PMA applications from hospitals that remanufacture SUD's. This figure has been included in table 1 of this document as part of the reporting burden in § 814.15.

The total estimated reporting and recordkeeping burden for this information collection is 107,321 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 | 62 | 1 | 62 | 837 | 51,894 |
| 814.39(f) | 487 | 1 | 487 | 66 | 32,142 |
| 814.82 | 43 | 1 | 43 | 66 | 5,805 |
| 814.84 | 43 | 1 | 43 | 10 | 430 |
| 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 |
| Totals | | | | | 92,021 |

[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 per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 814.82(a)(5) and (a)(6) | 900 | 1 | 900 | 17 | 15,300 |
| Totals | | | | | 15,300 |

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

The industry-wide burden estimate for PMA's is based on an FDA actual average fiscal year annual rate of receipt of 62 PMA original applications and 487 PMA supplements, using fiscal year 1996 through 2000 data.

The burden data for PMA's 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: (1) Clinical investigations: 67 percent of total burden estimate; (2) submission of additional data or information to FDA during a PMA review: 12 percent; (3) additional device development cost (e.g., testing): 10 percent; and (4) PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data: 11 percent.

**II. 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.

*A. Reporting/Disclosure*

The reporting burden can be broken out by certain sections of the PMA regulation: (1) § 814.15 *Research conducted outside the United States*; (2) § 814.20 *Application*; and (3) § 814.37 *PMA amendments and resubmitted PMA's*.

The majority of the burden—51,894 burden hours—is due to the above 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 62 manufacturers (including hospital re-manufacturers of single use devices) will be affected by these requirements based on actual average FDA receipt of new PMA applications in years 1996 through 2000. FDA's estimate of the hours per response (837) was derived through FDA's experience and consultation with 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.

1. § 814.39(f)—PMA Supplements: 32,142 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 ten percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 32,142 hours of burden are needed to complete the requirements for regular PMA supplements.

2. § 814.82—*Postapproval requirements*: 5,805 Burden Hours

Postapproval requirements concern approved PMA's that were not reclassified and require a periodic report. In the last decade (1991 to 2000), the range of PMA's that fit this category averaged approximately 43 per year (70 percent of the 62 periodic submissions). Most approved PMA's have been subject to some post approval study requirement. Approximately half of the average submitted PMA's (31) 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 PMA's require minimal information. Based on its experience and on consultation with industry, FDA estimates that preparation of reports and information required by this section require 5,805 hours (135 hours per respondent).

3. § 814.84—*Reports*: 430 Burden Hours

Postapproval requirements described in § 814.82 (above) require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on a periodic basis. As stated previously, the range of PMA's fitting this category averaged approximately 43 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 this section take 430 hours.

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.

*B. 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 PMA's are eventually approved and 75 percent of those have original clinical trial data. Therefore, approximately 43 PMA's a year (62 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMA's, all holders of active PMA applications must maintain these records. PMA's have been required since 1976, and there are 900 active PMA's 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 900 holders of approved original PMA's, therefore, is 15,300 hours (900 approved PMA's 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: February 2, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01–3323 Filed 2–7–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 96M–0311]**

### Agency Information Collection Activities; Announcement of OMB Approval; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 18, 2000 (65 FR 62359), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0456. The approval expires on January 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 2, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01–3320 Filed 2–7–01; 8:45 am]

**BILLING CODE: 3510–22–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99D–0239]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Request for Resolution of Scientific Disputes Concerning the Regulation of Medical Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by March 12, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (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.

### Request for Resolution of Scientific Disputes Concerning the Regulation of Medical Devices

Section 404 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) is intended to ensure that FDA has effective processes to resolve the scientific disputes that occasionally arise between FDA and the regulated industry. Section 404 of FDAMA added new section 562 to the Federal Food, Drug, and Cosmetic Act (the act) which requires FDA to establish, by regulation, a procedure under which a person who is a sponsor, applicant, or manufacturer may request a review of a scientific controversy, when no other provision of the act or regulation provides such review.

In a final rule issued in the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended 21 CFR 10.75 to reflect the provisions of FDAMA. Each affected FDA center is responsible for developing and administering its own processes for handling requests for section 404 of FDAMA reviews and is issuing a guidance document containing specific information of the type suggested by the comments. The draft guidance document outlines the requirements for persons who are sponsors, applicants, or manufacturers of medical devices and who wish to file a request for a review of a scientific dispute by the panel as set out in the guidance. Persons filing a request for review should provide a Center for Devices and Radiological Health ombudsman with a concise summary of the scientific issue in dispute, including a summary of the particular FDA action or decision to which the requesting party objects, any prior advisory panel action and the results of all efforts that have been made to resolve the dispute, and a clear articulated summary of the arguments and relevant data and information. They may also provide material outside the official administrative record and not in the possession of FDA at the time the decision or action in dispute was made if it has a significant bearing on the issue or related public health considerations. The information that is collected will form the basis for resolving the dispute between the requester and FDA.

The likely respondents to this collection of information are medical device sponsors, applicants, or manufacturers who have a scientific dispute with FDA and who request a review of the matter by the Medical Devices Dispute Resolution Panel.

In the **Federal Register** of April 27, 1999 (64 FR 22617), the agency requested comments on the proposed collection of information. No comments concerning the information collection were received.

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