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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
6	1	6	20	120

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

The Medical Devices Dispute Resolution Panel represents a new process for resolving scientific disputes. In arriving at the estimates in table 1 of this document for the burden imposed in connection with a request for review by the Medical Devices Dispute Resolution Panel, FDA considered the number and substance of similar appeals of various types made to FDA in recent years, knowledge of similar submissions, and discussions with manufacturers.

Dated: February 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–3319 Filed 2–7–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1604]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; OTC Test Sample Collection Systems for Drugs of Abuse Testing

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.

OTC Test Sample Collection Systems for Drugs of Abuse Testing—21 CFR Part 809 (OMB Control Number 0910–0368)—Extension

FDA has reclassified over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) subject to restrictions established in accordance with section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)(e).

The labeling requirements for certain in vitro diagnostic products require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results. The purpose of this regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

The most likely respondents to this information collection will be manufacturers of over-the-counter drugs of abuse test kits.

In the **Federal Register** of November 16, 2000 (65 FR 69314), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total Hours
809.10	20	1	20	100	2,000

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

Based upon submissions to the agency (premarket notifications, premarket approval applications, registration and listing), FDA estimates that there will be about 20 manufacturers of these devices.

FDA estimates, based upon discussions with manufacturers of similar devices required to comply with 21 CFR 809.10, that it will take approximately 40 hours to gather the information required by the rule, 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling as necessary.

Dated: February 2, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–3322 Filed 2–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration, DHHS.

[Document Identifier: HCFA–6401]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.