investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three committee chairpersons who were selected from different geographical areas and of varying levels of Radioactive Drug Research Committee membership and activities. These chairpersons were asked for their assessment of time expended, cost, and views on completing the necessary reporting forms.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2914	96	1.0	96	1	96
361.1(c)(3)	FDA 2915	63	5	315	3.5	1,103
361.1(d)(5)		63	5	315	0.1	31
361.1(d)(8)		63	5	315	0	0
Total						1,230

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Form	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
361.1(c)(2)	FDA 2914 and 2915	96	1 per quarter 4 per year	10	960
Total					960

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–262 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1425]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Human Tissue Intended for Transplantation

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 (PRA).

DATES: Submit written comments on the collection of information by February 5, 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: 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 compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Tissue Intended for Transplantation—Part 1270 (21 CFR Part 1270)—(OMB Control Number 0910–0302)—Extension

Under section 361 of the Public Health Service Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus 1 and 2, hepatitis B, and hepatitis C through human tissue intended for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed. Section 1270.31(a) and (b) require written procedures to be prepared and followed for: (1) All significant steps in the infectious disease testing process, and (2) all significant steps in reviewing the relevant medical record of the donor. Any deviation from the written procedures are to be recorded and justified. Section 1270.33(a) requires records to be maintained concurrently with the performance of each significant step in infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records be retained regarding the determination of the suitability of the donors and such records required under §1270.21. Section 1270.33(h) requires all records be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration of the tissue, whichever is latest. Section 1270.35 requires specific records to be maintained to document: (1) The results and interpretation of all required infectious disease tests and results, (2) the identity and relevant medical records of the donor, (3) the receipt and distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue-based products. The following estimated numbers of establishments, donors, and products, which are based on information provided by industry associations, including the Eye Bank Association of America 1999 Eye Banking Statistical Report, revise the numbers from the 60-day notice (65 FR 48245, August 7, 2000). There are approximately 224 tissue establishments currently in operation, 110 conventional tissue banks and 114 eye tissue banks. There are an estimated total of 750,000 conventional tissue products and 86,900

eye tissue products manufactured per year. In addition, there are an estimated 20,000 donors of conventional tissue and 43,800 donors of eye tissue each year, with an estimated 45,500 and 14,600 unsuitable donors of conventional tissue and eye tissue, respectively.

On July 29, 1997 (62 FR 40429), FDA issued a final rule on human tissue intended for transplantation, part 1270, which finalized the interim rule implemented on December 14, 1993 (58 FR 65514). At that time, accredited members of the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA) were adhering to the standards of those organizations, which were comparable to recordkeeping requirements in part 1270, and were thus already in compliance with the interim rule. In 1997, we estimated that approximately 99 percent of the 170 tissue establishments (60 conventional tissue banks and 110 eye banks) then in operation, or 168 establishments, were accredited members of AATB and EBAA. Therefore, recordkeeping by these 168 establishments is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden below, thus, is estimated for the remaining 56 establishments (224 - 168 = 56).

The requirement for the development of written procedures under § 1270.31(a) and (b) is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. FDA also assumes that no new tissue banks will begin operation in the next 3 years. Therefore, the information collection burden under § 1270.31(a) and (b) is for the general review and update of written procedures, and the recording and justifying of any deviations from the written procedures, which we estimate to be an annual average of 24 hours for all written procedures per establishment. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h) include documenting the results and interpretation of all required infectious disease tests and results and the identify and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates below for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

In the **Federal Register** of August 7, 2000 (65 FR 48245), FDA published a 60-day notice requesting public comment on the information collection provisions. One letter of comment was received in response to the 60-day notice.

The comment stated that the requirements for written procedures represent ongoing, not one-time, costs, in part because written procedures must be periodically reviewed and updated.

FDA agrees that the review and update of written procedures are part of the information collection burden associated with the recordkeeping requirements and revised estimates are reflected in table 1 of this document.

The comment stated that there are costs associated in preparing different formats to comply with FDA requirements and tissue bank association standards.

The provisions in part 1270 do not require that data be prepared in a specified recordkeeping format. Separate records for the same or similar information are not necessary.

The comment also noted that there are other additional costs and recordkeeping burdens associated with an FDA inspection in that an establishment must review its records at that time.

The regulations do not impose any additional recordkeeping requirements during inspections. Costs incurred by establishments during an inspection are beyond the scope of this PRA analysis.

The comment was also concerned that the regulations created a burden by necessitating the direct observation of all testing performed by a contract laboratory.

The requirement to have written procedures for and to document all significant steps in the infectious disease testing process does not require an establishment to directly observe the performance of all medical tests to ensure compliance with part 1270. A tissue establishment may have a written procedure for ensuring that contract laboratories comply with the testing requirements in part 1270, such as the requirement that laboratories are using FDA licensed tests, are Clinical Laboratory Improvement Amendments certified, and follow manufacturers instructions for performing the required tests. For example, an establishment may write a procedure that would include performance of a periodic audit or to review a laboratory's standard operating procedures (SOP's) to ensure compliance with part 1270.

The comment also discussed the regulation's economic impacts, such as equipment costs and general operating costs, which go beyond the scope of information collection provisions. However, FDA will consider such issues when reviewing comments to the proposed rule on suitability determination for donors of human cellular and tissue-based products (64 FR 52696, September 30, 1999), which is intended to replace part 1270 when finalized.

TABLE 1. — ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1270.31(a) and 1270.31(b)[2]	56	1	56	24.0	1,344
1270.31(a) and 1270.31(b)[3]	56	2	102	1.0	102
1270.33(a), (f), and (h), and 1270.35(a) and (b)	56	195.57	10,952	1.0	10,952
127.35(c)	56	6,222.79	348,476	1.0	348,476
1270.35(d)	56	384.18	21,514	1.0	21,514
Total					382, 388

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Review and update of SOP's.
[3]Documentation of deviations from SOP's.

Dated: December 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–263 Filed 1–4–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1494]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Classification/ Reclassification; Restricted Devices: Analyte Specific Reagents

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 February 5, 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.

Medical Devices: Classification/ Reclassification; Restricted Devices; Specific Reagents—21 CFR Part 809 (OMB Control No. 0910–0361)— Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) establishes certain labeling requirements for devices including requirements that the labeling not be false or misleading in any particular, that the labeling contain the established name for the device, and that the labeling contain adequate directions for use. Section 520(e) of the act (21 U.S.C. 360j(e)) provides that FDA may restrict the sale, distribution, or use of a device, if FDA determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Section 502(q) and (r) of the act authorizes FDA to regulate the advertising of devices that are restricted under section 520(e) of the act.

FDA restricts distribution of analyte specific reagents (ASR's) to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing, to manufacturers of in vitro diagnostic products, and to organizations that use the tests for reasons other than providing diagnostic information to practitioners and patients. FDA has established certain labeling requirements for suppliers of ASR's and certain requirements regarding advertising and promotional materials for ASR's. FDA believes the labeling requirements and restrictions on advertising and promotion are necessary to ensure that laboratories developing tests from ASR's have sufficient information to use the ASR's appropriately and to limit specific claims by manufacturers, because these ASR's are intended to be used as ingredients in a variety of ways by laboratories qualified to do high complexity testing.

The most likely respondents to this information collection will primarily be medical device manufacturers of in vitro products, clinical laboratories, and other manufacturers of ASR's.

In the **Federal Register** of September 14, 2000 (65 FR 55633), the agency requested comments on the proposed collection of information. One comment, discussing three separate issues, was received.

1. The comment first asked that medical device manufacturers provide basic laboratory instructions for use and warn against uses that are not appropriate for the particular ASR.

FDA was not persuaded by this comment. The intention of the ASR rule is to ensure that laboratories using these products to develop in-house or ''home brew'' tests take full responsibility for the development of the ''home brew'' test and for the characterization of test performance for the ASR based test. ASR use is restricted to high-complexity laboratories under the CLIA which have the ability to develop tests based on their own experience or the medical literature. The instructions for use in different laboratories using ASR's would be expected to vary with the experience of the laboratory and with the information obtained during test development and characterization.

If a medical device manufacturer wishes to provide laboratory instructions on product use, this is acceptable. However, this is evidence that a kit or system is being marketed rather than used as an ASR or building block for an assay. Such a device would not be exempt from premarket review by FDA.

2. The comment further indicated that a guidance or written clarification as to the scope of appropriate warnings and precautions would be helpful.

FDA does not believe such guidance or written clarification is necessary. The regulation in 21 CFR 809.10(e)(1)(v) requires ''A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part