Supporting Statement for
Human Tissue Intended for Transplantation
0910-0302

JUSTIFICATION

1. Need and Legal Basis

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0302, and OMB approval of the information collection requirements in 21 CFR Part 1270 (Tab A), Human Tissue Intended for Transplantation, listed below:

21 CFR 1270.31(a) through (d)	Recordkeeping	Requires written procedures to be prepared and followed for the following steps: (a) All significant steps in the infectious disease testing process, (b) all significant steps in obtaining, reviewing, and assessing the relevant medical record of the donor, (c) designating and identifying quarantined tissue, and (d) for preventing infectious disease contamination or cross-contamination of tissues during processing. Section (a) and (b) also require recording and justification of any deviation from the written procedures.
21 CFR 1270.33(a)	Recordkeeping	Requires records to be maintained concurrently with the performance of each significant step in the procedures of infectious disease screening and testing of human tissue donors.
21 CFR 1270.33(f)	Recordkeeping	Requires records to be retained regarding the determination of the suitability of the donors and such records required under §1270.21.
21 CFR 1270.33(h)	Recordkeeping	Requires all records to be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration of the tissue, whichever is latest.
21 CFR 1270.35 (a) through (d)	Recordkeeping	Requires specific records to be maintained to document the following: (a) The results and interpretation of all required infectious disease tests; (b) information on the identity and relevant medical records of the donor; (c) the receipt and/or distribution of human tissue; and, (d) the destruction or other disposition of human tissue.

Under section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) (Tab B), FDA issued regulations to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, hepatitis C, and other organisms causing infectious disease through the use of human tissue for

2006N-0475

SS 1

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 provisions intended to ensure appropriate screening and testing of human tissue donors and ensure that records are kept documenting that the appropriate screening and testing have been completed.

2. Information Users

These information collection requirements help prevent the transmission of communicable diseases through human tissue transplantation by requiring that written SOPs be prepared and followed for the following: (1) infectious disease testing, (2) determining the medical history of each donor, (3) designating and identifying quarantined tissue, and (4) preventing the contamination or cross-contamination of tissue during processing. The regulations require maintenance of records of all significant steps in testing, processing, and distribution or final disposition of the tissue, and allow FDA inspection of the persons, records and tissue establishments involved in the above processes. Adequate donor screening and testing must be recorded so that the suitability of the tissue can be determined. If FDA is unable to ascertain how the tissue donor was screened or tested, or if the tissue was distributed in violation of the regulations, then recall, retention, and/or destruction orders may be issued by FDA in accordance with codified administrative procedures. Without this information collection, FDA could not monitor the suitability of human tissue for transplantation and could not fulfill its statutory responsibility to ensure that communicable diseases are not spread into or throughout the United States and its Possessions.

3. Improved Information Technology

Establishments may use computers, computer tapes or discs, microfiche, or microfilm to record and store data and information rather than hard copy records. The use of this technology is specifically referenced in the regulations under § 1270.33(g). Section 1270.33(f) considers that the retrieval of records from another location by electronic means meets the requirements of the regulation. FDA is not aware of any other improved technology to reduce the burden.

4. Duplication of Similar Information

FDA is the only agency that requires this information. There is no similar kind of information available from any other source.

5. Small Businesses

Although FDA must apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research's (CBER), Office of Communication, Training, and Manufacturer's Assistance provides assistance to small businesses subject to FDA's regulatory requirements.

6. Less Frequent Collection

The information provided by the records for each tissue, at the time it is recovered, screened, tested, processed, stored or distributed, is used to determine the suitability of the human tissue for transplantation and for its final distribution or disposition. Less frequent collection of information would not ensure the safety of the tissue supply in this country. The information provides to FDA inspectors the information necessary to fulfill FDA's statutory responsibility to prevent the spread of communicable diseases. FDA would be unable to fulfill these duties with less frequent information collection.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances

There is no special circumstance for the collection of information requirements.

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the FEDERAL REGISTER of December 4, 2006 (71 FR 70410). No comments were received from the public.

9. Payment/Gift to Respondent

No payment or gift was provided to respondents.

10. Confidentiality

The confidentiality of information received by FDA is consistent with the Freedom of Information Act and the FDA's regulations under 21 CFR Part 20. Inspectors may copy records as part of the inspection of a tissue establishment. Such information may be copied to document distribution of potentially infectious tissue. This information is for internal use and will be redacted from any information released by FDA under the Freedom of Information Act and FDA regulations.

11. Sensitive Questions

Questions of a sensitive nature, such as sexual behavior and other matters that are commonly considered private, must be asked by the establishments as part of the donor medical history evaluation. The answers to these questions help determine the suitability of a donor. Donors that do not meet certain criteria would be deferred from donating. The collection of this information is necessary to prevent the transmission of communicable diseases and to protect the public health. Records of such information may be reviewed by FDA during an inspection.

12. Burden Estimate (Total Hours and Wages)

The estimated annual burden for this information collection is 783,322 hours.

Table 1. -- Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1270.31(a) through (d)	2	1	2	64	128
1270.31(a) through (d)[1]	28	1	28	24	672
1270.31(a) and 1270.31(b)[2]	28	2	56	1	56
1270.33(a), (f), and (h), and 1270.35(a) and (b)	28	8,843	247,610	1	247,610
1270.35(c)	28	16,980	475,436	1	475,436
1270.35(d)	28	2,123	59,430	1	59,430
Total					783,332

1 Review and update of SOPs

2 Documentation of deviations from SOPs

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from FDA's CBER database system, FDA estimates that there are approximately 190 tissue establishments of which 105 are conventional tissue banks and 85 are eye tissue banks. Based on information provided by industry, there are an estimated total of 1,500,000 conventional tissue products and 84,789 eye tissue products recovered per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 23,295 donors of conventional tissue and 42,649 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirement in Part 1270. Based on information provided by CBER's database system, 76 percent of the conventional tissue banks are members of AATB (105 X 76 percent = 80), and 96 percent of eye tissue banks are members of EBAA (85 X 96 percent = 82). Therefore, recordkeeping by these 162 establishments (80 + 82 = 162) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 28 establishments, which is 15 percent of all establishments (190 - 162 = 28, or 28/190 = 15 percent).

Based on CBER's database system and information provided by industry, FDA estimates an average of two new tissue banks annually, which may be non-members of a trade association. Each new tissue bank requires an estimated 64 hours to prepare standard operating procedures (SOPs) under § 1270.31(a) through (d). The requirement for the development of these written procedures is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with Part 1270. Therefore,

their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures for 21 CFR 1270.31(a) and (b), estimated to take an annual average of 1 hour. 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 identity 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 for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

Cost to Respondents

The estimated annual cost to respondents is $27,416,270.

Activity	No. of Hours	Cost per Hour	Total Cost
Recordkeeping	783,322	$35	$27,416,270

The cost estimate is based on a Donor Coordinator, at a pay rate of $35/hour who is responsible for maintaining accurate records for each of the units of tissue received, processed, and distributed annually. This salary estimate includes benefits but no overhead costs.

13. Capital Costs (Maintenance of Capitol Costs)

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to the Federal Government

The estimated annual cost to the Federal Government is $190,000. There are approximately 190 manufacturers of conventional tissue and eye tissue that will be inspected on a biennial basis. Therefore, it is estimated that approximately half (95 establishments) will be inspected annually. The cost estimate is based on a FDA inspector at an average grade of GS-12/5 ($40/hour), who takes an average of 50 hours for each establishment to perform the on-site inspection, review of its records, and the report write-up.

Activity	Number of Respondents	Hours per Respondent	Cost per Hour	Total Cost
Inspection	95	50	$40	$190,000

15. Program or Burden Changes

The previous burden estimate was 592,166 hours. The increase in burden to 783,322 hours is mostly attributed to an increase in the number of total annual records (590,426 to 782,426) under §§ 1270.33 and 1270.35.

16. Publication and Tabulation Dates

There are no tabulated results to publish for this information collection.

17. Display of OMB Approval Date

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Explanations to "Certification for Paperwork Reduction Act Submissions"

Not Applicable.