Human Tissue Intended for Transplantation

OMB# 0910-0302

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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, 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 under § 1270.21; (b) all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as prescribed in § 1270.21; (c) designating and identifying quarantined tissue; and (d) for prevention of infectious disease contamination or cross-contamination of tissues during processing.
21 CFR 1270.31(a) and (b)	Recordkeeping	Requires 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 performance 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 if known, distribution, disposition, or expiration of the tissue, whichever is the 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 Services (PHS) Act (42 U.S.C. 264), FDA issued regulations under part 1270 (21 CFR 1270) to prevent the transmission of human

immunodeficiency virus (HIV), hepatitis B and hepatitis C, and other organisms causing infectious disease through the use of 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 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. Purpose and Use of the Information Collection

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 the donor; (3) designating and identifying quarantined tissue; and (4) preventing infectious disease contamination or cross-contamination of tissue during processing. The regulations require maintenance of records of all significant steps in the infectious disease testing, and screening, and require that these records be made available for FDA inspection. 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. Use of Improved Information Technology and Burden Reduction

Establishments may maintain records electronically or as original paper records, or as true copies such as photocopies, microfiche, or microfilm. Electronic recordkeeping is specifically referred to 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. Efforts to Identify Duplication and Use 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. Impact on Small Businesses or Other Small Entities

This collection of information applies to small as well as large establishments. 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, Outreach and Development, Division of Manufacturer's Assistance and Training provides assistance to small businesses.

6. Consequences of Collecting the Information Less Frequently

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. The information provided to FDA inspectors is the information necessary to fulfill FDA's statutory responsibility to prevent the spread of communicable diseases. Less frequent collection of information would not ensure the safety of the tissue supply in this country or enable FDA to fulfill these duties.

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

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of information requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of July 10, 2013 (78 FR 41403). One letter of comment was received from a trade organization. The comment requested that the notice be corrected to reflect that an estimated total of 1,959,720 conventional tissue products are distributed (not recovered) per year. The comment also requested a revision in the number of donors of conventional tissues based on the American Association of Tissue Banks (AATB) Annual Survey 2007. FDA agrees with these comments and has made the recommended changes.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and the FDA's published regulations of "Public Information" under 21 CFR Part 20. Inspectors may copy records as part of an inspection of a tissue establishment. This information is for internal use and may be subject to, in whole or in part, the FOIA and applicable FDA regulations.

11. Justification for 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. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The estimated annual burden for this information collection is 806,770 hours.

Table 1. -- Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1270.31(a), (b), (c), and (d)[1]	33	1	33	24	792
1270.31(a) and (b)[2]	33	2	66	1	66
1270.33(a), (f), and (h), and 1270.35(a) and (b)	33	7,714.24	254,570	1	254,570
1270.35(c)	33	14,850.96	490,082	1	490,082
1270.35(d)	33	1,856.36	61,260	1	61,260
Total					806,770

[1] Review and update of standard operating procedures (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 281 tissue establishments of which 185 are conventional tissue banks and 96 are eye tissue banks. Based on information provided by industry, there are an estimated total of 1,959,270 conventional tissue products and 82,741 eye tissue products distributed per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 30,380 donors of conventional tissue and 49,026 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, 90 percent of the conventional tissue banks are members of AATB (185 x 90 percent = 166), and 85 percent of eye tissue banks are members of EBAA (96 x 85 percent = 82). Therefore, recordkeeping by these 248 establishments (166 + 82 = 248) 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 33 establishments, which is 12 percent of all establishments (281 - 248 = 33, or 33/281 = 12 percent).

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 under § 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.

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $32,270,800.

Activity	No. of Hours	Cost per Hour	Total Cost
Recordkeeping	806,770	$40	$32,270,800

The cost estimate is based on a Donor Coordinator, at a pay rate of $40/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. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal Government is $401,850. There are approximately 281 manufacturers of conventional tissue and eye tissue that will be inspected on a biennial basis. Therefore, it is estimated that approximately half (141 establishments) will be inspected annually. The cost estimate is based on a FDA inspector at an average grade of GS-13/5 ($57/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	141	50	$57	$401,850

15. Explanation for Program Changes or Adjustments

The previous burden estimate in 2011 was 1,080,760 hours. The decrease in burden to 806,770 (~ 273,990) hours is mostly attributed to a decrease in the number of establishments and a

corresponding decrease in the number of total annual records under all the listed regulations including a slight decrease due to the revised number of 30,380 donors of conventional tissues used for the estimates under §§ 1270.33(a), (f), and (h), and 1270.35(a) and (b).

16. Plans for Tabulation and Publication and Project Time Schedule

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

17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.