



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0797]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0302. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

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--21 CFR Part 1270

OMB Control Number 0910-0302--Extension

Under section 361 of the Public Health Services Act (42 U.S.C. 264), FDA issued regulations under part 1270 (21 CFR part 1270) to prevent the transmission of human immunodeficiency virus, hepatitis B, and hepatitis C, through the use of human tissue 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 to ensure that records are kept documenting that the appropriate screening and testing have been completed.

Section 1270.31(a) through (d) (21 CFR 1270.31(a) through (d)) requires written procedures to be prepared and followed for the following steps: (1) all significant steps in the infectious disease testing process under § 1270.21 (21 CFR 1270.21); (2) all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as prescribed in § 1270.21; (3) designating and identifying quarantined tissue; and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Section 1270.31(a) and (b) also requires recording and justification of any deviation from the written procedures. Section 1270.33(a) (21 CFR 1270.33(a)) requires records to be maintained concurrently with the performance of each significant step required in the performance of infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records to be retained regarding the determination of the suitability of the donors and of the records required under § 1270.21.

Section 1270.33(h) requires all records to be retained for at least 10 years beyond the date of transplantation, if known, distribution, disposition, or expiration of the tissue, whichever is the latest. Section 1270.35(a) through (d) (21 CFR 1270.35(a) through (d)) requires specific records to be maintained to document the following: (1) the results and interpretation of all required infectious disease tests; (2) information on the identity and relevant medical records of the donor; (3) the receipt and/or 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 intended for transplantation. Based on information from the Center for Biologics Evaluation and Research's (CBER's) database system, we estimate 383 tissue establishments, of which 262 are conventional tissue banks and 121 are eye tissue banks. Based on information provided by industry, we estimate a total of 2,141,960 conventional tissue products, and 130,987 eye tissue products distributed per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, we estimate 29,799 deceased donors of conventional tissue and 70,027 deceased 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 requirements in part 1270. Based on information included in CBER's database system, 90 percent of the conventional tissue banks are members of AATB ($262 \times 90 \text{ percent} = 236$), and 95 percent of eye tissue banks are members of EBAA ($121 \times 95 \text{ percent} = 115$). Therefore, we exclude burden for recordkeeping by these 351 establishments ($236 + 115 = 351$) from our estimate as we believe such recordkeeping is usual and customary business activity (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the

remaining 32 establishments, which is 8.36 percent of all establishments (383 – 351 = 32, or 32/383 = 8.36 percent).

We assume that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, our estimated burden includes the general review and update of written procedures (an annual average of 24 hours), and the recording and justifying of any deviations from the written procedures under § 1270.31(a) and (b) (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 our experience with the information collection.

In the *Federal Register* of September 24, 2019 (84 FR 50039), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this information collection as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR part 1270; Human Tissue Intended for Transplantation	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart C--Procedures and Records					
1270.31(a) through (d) ²	32	1	32	24	768
1270.31(a) and (b) ³	32	2	64	1	64
1270.33(a), (f), and (h), and 1270.35(a) and (b)	32	6,198.84	198,363	1	198,363
1270.35(c)	32	11,876.12	380,036	1	380,036
1270.35(d)	32	1,484.50	47,504	1	47,504

Total	626,735
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¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²Review and update of standard operating procedures (SOPs).

³Documentation of deviations from SOPs.

Based on a review of the information collection since our last OMB approval, we have made no adjustments to our burden estimate.

Dated: January 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-00144 Filed: 1/8/2020 8:45 am; Publication Date: 1/9/2020]