

Section 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) 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, FDA estimates that there are approximately 383 tissue establishments, of which 262 are conventional tissue banks and 121 are eye tissue banks. Based on

information provided by industry, there are estimated totals 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, there are an estimated 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 provided by CBER's database system, 90 percent of the conventional tissue banks are members of AATB ($262 \times 90\% = 236$), and 95 percent of eye tissue banks are members of EBAA ($121 \times 95\% = 115$). Therefore, recordkeeping by these 351 establishments ($236 + 115 = 351$) 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 32 establishments, which is 8.36 percent of all establishments ($383 - 351 = 32$, or $32/383 = 8.36\%$).

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. The recordkeeping estimates 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 June 6, 2016 (81 FR 36310), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1270.31(a), (b), (c), and (d) ²	32	1	32	24	768
1270.31(a) and 1270.31(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

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

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

³ Documentation of deviations from SOPs.

Dated: October 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a

forthcoming public advisory committee meeting of the Science Board to the Food and Drug Administration. The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda and on upgrading its scientific and research

facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs. The meeting will be open to the public.

DATES: The meeting will be held on November 15, 2016, from 8:30 a.m. until 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section C), Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at <https://collaboration.fda.gov/sbm1116/>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301-796-4769, rakesh.raghuwanshi@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The Science Board will hear about: (1) The Center for Biologics Evaluation and Research's strategic goals for regulatory science; (2) a progress update on FDA's Opioid Action Plan and the Bovine Heparin Initiative; (3) a response from the Office of Scientific Professional Development to the Science Board's report on the Commissioner's Fellowship Program; (4) a report from the Scientific Engagements Subcommittee; (5) and a report from the Food Emergency Response Network Cooperative Agreement Program Evaluation Subcommittee.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 8, 2016. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 2, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 4, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rakesh Raghuwanshi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 28, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 2, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Telehealth Outcome Measures OMB No. 0915-0311—Revision.

Abstract: To help carry out its mission, the Office for the Advancement of Telehealth (OAT) created a set of performance measures that grantees use to evaluate the effectiveness of their services programs and monitor their progress through the use of performance reporting data.

Need and Proposed Use of the Information: As required by the Government Performance and Results Act of 1993, all federal agencies must develop strategic plans describing their overall goal and objectives. HRSA's