

may not conduct or sponsor a collection of information unless it displays a currently valid control number. Notwithstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Questions concerning this revised information collection should be directed to Leslie F. Smith, Federal Communications Commission, (202) 418-0217 or via the Internet at Leslie.Smith@fcc.gov.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04-1530 Filed 1-23-04; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2640-Correction]

Petition for Reconsideration and Clarification of Action in Rulemaking Proceedings

January 7, 2003.

Petitions for Reconsideration and Clarification have been filed in the Commission's Rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of this document is available for viewing and copying in Room CY-A257, 445 12th Street, SW., Washington, DC, or may be purchased from the Commission's copy contractor, Qualex International (202) 863-2893. Oppositions to these petitions must be filed by February 10, 2004. See 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions have expired.

Subject: In the Matter of the Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996 (CC Docket No. 96-128).

Number of Petitions Filed: 4.

* This is a correction to Report #2640, released on December 23, 2003, to include an additional petition which was inadvertently omitted from CC Docket No. 96-128. The dates for filing oppositions will be extended to 15 days from the date of publication of this notice in the **Federal Register**. Replies to an opposition will be extended to 10

days after the time for filing oppositions has expired.

Marlene H. Dortch,

Secretary.

[FR Doc. 04-1529 Filed 1-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0404]

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 February 25, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezuto, Office of Management Programs (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—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 (HIV), 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)) require written procedures to be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process, (2) all significant steps in reviewing the relevant medical record of the donor, (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 require 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 in the procedures 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 such records required under 21 CFR 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 (21 CFR 1270.35) requires specific records be maintained to document the following outcomes: (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 intended for transplantation. Based on information from FDA's Center for Biologics Evaluation and Research (CBER) database system, the agency estimates that there are approximately 300 tissue establishments of which 166 are conventional tissue banks and 134 are eye tissue banks. Based on information provided by industry, there are an estimated total of 750,000 conventional tissue products and 94,186 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 20,000 donors of conventional tissue and 47,796 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 (21 CFR part 1270). Based on information provided by industry associations, 50 to 75 percent (average 63 percent) of the conventional tissue banks are members of AATB (166×63 percent = 105), and 99 percent of eye tissue banks are members of EBAA (134×99 percent = 133). Therefore, recordkeeping by these 238 establishments ($105 + 133 = 238$) 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 62 establishments, which is

21 percent of all establishments ($300 - 238 = 62$, or $62/300 = 21$ 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 nonmembers 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 § 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 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 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 October 1, 2003 (68 FR 56635), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

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) ²	62	1	62	24	1,488
1270.31(a) and (b) ³	62	2	124	1	124
1270.33(a), (f), and (h) and 1270.35(a) and (b)	62	3,089	191,518	1	191,518
1270.35(c)	62	5,719	354,578	1	354,578
1270.35(d)	62	715	44,330	1	44,330
Total					592,166

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: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-1493 Filed 1-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0329]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How To Use E-Mail To Submit Information to the Center for Veterinary Medicine

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.

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FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management