distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products.

The respondents for this collection of information are manufacturers and or distributors of products that contain or may contain protein derived from mammalian tissues and feeds made from such products.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
589.2000 (e)(1)(iv)	400	1	400	14	5,600

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

Dated: November 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy

[FR Doc. E6–20476 Filed 12–01–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0475]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for human tissue intended for transplantation.

DATES: Submit written or electronic comments on the collection of information by February 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Tissue Intended for Transplantation—21 CFR Part 1270 (OMB Control Number 0910–0302)—Extension

Under section 361 of the Public Health Service (PHS) 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.

Sections 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 obtaining, reviewing, and assessing the relevant medical records of the donor; (3) designating and identifying quarantined tissue; and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Sections 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 § 1270.21 (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 the latest. Section 1270.35 (21 CFR 1270.35) requires specific

records 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 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 21 CFR 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 § 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1270.31(a), (b), (c), and (d)	2	1	2	64	128
1270.31(a), (b), (c), and (d)[2]	28	1	28	24	672
1270.31(a) and 1270.31(b)[3]	28	2	46	1	46
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					783,322

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Review and update of SOPs.
[3]Documentation of deviations from SOPs.

Dated: November 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–20477 Filed 12–01–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0494]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

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 January 3, 2007.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.