FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act—(OMB Control Number 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of July 9, 2013 (78 FR 41065), FDA published a 60-day notice requesting public comment on the proposed collection of information to which one comment was received but was unrelated to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for Accreditation	1	1	1	24	24
510(k) Reviews Conducted by Accredited Third Parties	10	26	260	40	10,400
Total					10,424

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

510(k) Reviews Conducted by Accredited Third Parties

According to FDA's data, the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews	10	26	260	10	2,600

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

Third-party reviewers are required to keep records of their review of each submission. According to FDA's data, the Agency anticipates approximately 260 submissions of 510(k)s for third-party review per year.

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–29010 Filed 12–3–13; 8:45 am]

BILLING CODE 4160–01–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 January 3, 2014.

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 *oira_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: FDA PRA Staff, Office of Operations, Food

and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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 (PHS) 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) requires written procedures be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process under § 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) 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) 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 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 requirements in part 1270. Based on information provided by CBER's database system, 90 percent of the conventional tissue banks are members of AATB (185 × 90 percent = 166), and 85 percent of eye tissue banks are members of EBAA (96 × 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.

In the **Federal Register** of July 10, 2013 (78 FR 41403), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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 1,959,270 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 AATB Annual Survey 2007. FDA agrees with these comments and made the recommended changes.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Part	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]	33	1	33	24	792
1270.31(a) and 1270.31(b) [3]	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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					806,770

[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: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28989 Filed 12–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1428]

Draft Guidance for Industry on Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Quality and Security Act (DQSA), and sets forth an interim electronic submission method for human drug compounders that choose to register as outsourcing facilities (outsourcing facilities).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on a draft guidance describing the updated format for long-term use, submit either electronic or written comments on this draft guidance by February 3, 2014. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by February 3, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Drug Registration and Listing Team, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance is being issued to implement new provisions added to the FD&C Act in the DQSA. In the newly enacted legislation, Congress created a new statutory category of ''outsourcing facilities'' that compound drugs. New section 503B of the FD&C Act (21 U.S.C. 353b) allows compounders to register with FDA as outsourcing facilities and, among other things, imposes reporting requirements on these entities if they choose to register. The draft guidance is intended to assist registered outsourcing facilities in implementing drug reporting. The draft guidance describes how an outsourcing facility should provide interim electronic reports while FDA modifies its existing electronic drug registration and listing system to accommodate reporting of product information by registered outsourcing facilities under section 503B of the FD&C Act. When the Agency has modified its current electronic submission system to allow outsourcing facilities to submit information electronically through a Structured Product Labeling file, FDA intends to issue a draft guidance describing the updated format for long-term use. When such guidance is issued in final form, it will specify the form of reporting that outsourcing facilities are to follow from that point forward.

The draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Elsewhere in this issue of the **Federal Register**, the Agency is making available for comment a draft guidance on registration for human drug compounding outsourcing facilities under section 503B of the FD&C Act.

II. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (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 that 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** for each proposed 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 collection of information associated with this document, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3)