products posted between April 12, 2019, and September 23, 2019, available on FDA's website at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm* but not presented at the September 26 or 27, 2019, Joint PAC or DSaRM meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108–155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA–2019–N–1215. The docket will open on September 23, 2019, and remain open until October 7, 2019. The post-marketing pediatric-focused safety reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

(1) GAMMAPLEX—Immune Globulin Intravenous (Human) 5% Liquid
(2) NUWIQ®—(simoctocog alfa)
(3) TACHOSIL®—Absorbable Fibrin Sealant Patch
(4) WILATE—von Willebrand Factor/Coagulation Factor VIII Complex (Human)

Center for Drug Evaluation and Research

(1) ATIVAN INJECTION—(lorazepam injection)
(2) E–Z–HD—(barium sulfate)
(3) LIQUID E–Z–PAQUE—(barium sulfate)
(4) READI–CAT 2 and READI–CAT 2 SMOOTHIE—(barium sulfate)
(5) VARIBAR PUDDING—(barium sulfate)
(6) CALCIUM GLUCONATE INJECTION—(calcium gluconate)
(7) CEREBYX®—(fosphenytoin sodium)
(8) DOTAREM—(gadoterate meglumine)
(9) FYCOMPA ORAL TABLETS AND SUSPENSION—(perampanel)
(10) HARVONI—(ledipasvir and sofosbuvir)
(11) ISENTRESS AND ISENTRESS HD—(raltegravir)
(12) LATUDA—(lurasidone hydrochloride)
(13) RAPIVAB®—(peramivir)
(14) RYZODEG 70/30—(insulin degludec and insulin aspart injection) for subcutaneous use 100 units/mL (U–100) in 3ml FlexTouch Pen
(15) SIMPONI—(golimumab SC) and SIMPONI ARIA (golimumab IV)
(16) SOVALDI—(sofosbuvir)
(17) STRIBILD—(elvitegravir, cobicistat, emtricitabine/tenofovir disoproxil fumarate)
(18) TRESIBA—(insulin degludec injection), for subcutaneous use, 100 units/mL (U–100) in 3ml single-patient-use FlexTouch Pen; 200 units/mL (U–200) in 3mL single-patient-use FlexTouch Pen; 100 units/mL (U–100) 10mL in multiple-dose vial
(19) VIGAMOX—(moxifloxacin hydrocholoride ophthalmic solution 0.5%)
(20) VISIPAQUE INJECTION—(iodixanol)
(21) ZEMPLAR—(paricalcitol)
(22) ZYMAR® 0.3%—(gatifloxacin ophthalmic solution)

Center for Devices and Radiological Health

(1) CONTEGRA PULMONARY VALVED CONDUIT—(Humanitarian Device Exemption [HDE])
(2) ELANA SURGICAL KIT—(HDE)
(3) ENTERRA THERAPY SYSTEM—(HDE)
(4) PLEXIMMUNE™ IN–VITRO DIAGNOSTIC TEST—(HDE)
(5) PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE—(HDE)

Dated: September 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20658 Filed 9–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0797]

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, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 either electronic or written comments on the collection of information by November 25, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 25, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0797 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, *PRAStaff@fda.hhs.gov.*

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 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) 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; (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. Sections 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, 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 × 90 percent = 236), and 95 percent of eye tissue banks are members of EBAA (121 × 95 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.

We estimate the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1270; human tissue intended for transplantation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart C—Procedures and Records					
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	1.0	198,363
1270.35(c)	32	11,876.12	380,036	1.0	380,036
1270.35(d)	32	1,454.50	47,504	1.0	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.

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

Dated: September 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20669 Filed 9–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–2123]

Determination That ATROPINE SULFATE ANSYR PLASTIC SYRINGE (Atropine Sulfate Solution) Intravenous, Intramuscular, Subcutaneous, and Endotracheal, 0.5 Milligram/5 Milliliters (0.1 Milligram/Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that ATROPINE SULFATE ANSYR PLASTIC SYRINGE (atropine sulfate solution) intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 milligram (mg)/5 milliliters (mL) (0.1 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for atropine sulfate solution intravenous, intramuscular, subcutaneous, and endotracheal, 0.5 mg/5 mL (0.1 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3702, *Carlarease.Hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.