Application No.	Drug	Applicant
ANDA 088897	Promethazine VC Plain (phenylephrine HCl and promethazine HCl) Syrup, 5 mg/5 mL and 6.25 mg/5 mL.	Do.
ANDA 089141	Aerolate (theophylline) Oral Solution, 150 mg/15 mL	Fleming and Co. Pharmaceuticals, Inc.
ANDA 089417	Methocarbamol Tablets USP, 500 mg	American Therapeutics, Inc.
ANDA 089418	Methocarbamol Tablets USP, 750 mg	Do.
ANDA 089478	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Do.
ANDA 089479	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Do.
ANDA 089480	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 089514	Trihexyphenidyl HCl Elixir, 2 mg/5 mL	Pharmaceutical Ventures, Ltd., P.O. Box D3700, Pomona, NY 10970.
ANDA 089726	Prednisone Oral Solution, 5 mg/5 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 204472	Fludeoxyglucose F–18 Injection USP, 20–300 mCi/mL	MIPS Cyclotron and Radiochemistry Facility, 1201 Welch Rd., Rm. PS049, Stanford, CA 94305.
ANDA 204517	Sodium Fluoride F–18 Injection, 10–200 mCi/mL	Do.
ANDA 204535	Ammonia N–13 Injection USP, 3.75–37.5 mCi/mL	Do.

Therefore, under §§ 314.150(b)(1) and 314.200 (21 CFR 314.150(b)(1) and 314.200), notice is given to the holders of the approved ANDAs listed in the table and to all other interested persons that the Director of CDER proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) withdrawing approval of the ANDAs and all amendments and supplements to them on the grounds that the ANDA holders have failed to submit reports required under §§ 314.81 and 314.98.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the ANDA holders are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for an administrative determination, all issues relating to the legal status of the drug products covered by these ANDAs.

An ANDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, the notice of participation and request for a hearing; the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: January 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00120 Filed 1–8–20; 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; 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 10, 2020.

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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 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) (21 CFR 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 (21 CFR 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. Section 1270.31(a) and (b) also requires 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 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) (21 CFR 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.

In the **Federal Register** of September 24, 2019 (84 FR 50039), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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) through (d) [2]	32	1	32	24	768
1270.31(a) and (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

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

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
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: January 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00144 Filed 1–8–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6085]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Administrative Practice and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 information collection associated with our General Administrative Practice and Procedures regulations.

DATES: Submit either electronic or written comments on the collection of information by March 9, 2020.

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 March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2020. 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–2019–N–6085 for ''General Administrative Practice and Procedures.'' 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.