

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holders are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for an administrative determination, all issues relating to the legal status of the drug products covered by these ANDAs.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]

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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 oir_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, PRASStaff@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 ($262 \times 90 \text{ percent} =$
236), and 95 percent of eye tissue banks
are members of EBAA ($121 \times 95 \text{ percent} =$
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
 $32/383 = 8.36 \text{ percent}$).

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.