

records regarding clinical investigators, including protocol agreements and investigator resumes or curriculum

vitae. FDA estimates that an average of 15 minutes will be required for each

recordkeeper to add this record to the clinical investigators' file.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours ²
Recordkeeping—54.6	715	1	715	0.25	179

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

² Numbers have been rounded.

Third-Party Disclosure Burden

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure

statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are

needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the median, 10 minutes, for the average burden per disclosure (see table 1).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours ²
54.4(b)—Clinical Investigators	13,082	1	13,082	0.17	2,224

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

² Numbers have been rounded.

The burden for this information collection request has changed since the last OMB approval. Our estimated burden for the information collection reflects a 298 hour increase. We have adjusted our estimated burden for the information collection to reflect the number of submissions we received in the last few years. Additionally, for products regulated by the Center for Devices and Radiological Health, we now include De Novo requests as a type of application that may rely on clinical studies. For products regulated by the Center for Drug Evaluation and Research, we now include biologics license applications (BLAs) and BLA efficacy supplements that were inadvertently excluded from our last information collection request as a type of application.

Dated: November 24, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-26182 Filed 12-1-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1145]

Aurolife Pharma LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 3, 2022.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 072514	Clorazepate Dipotassium Tablets, 3.75 milligrams (mg), 7.5 mg, and 15 mg.	Aurolife Pharma LLC, 2400 U.S. Hwy. 130 N, Dayton, NJ 08810.
ANDA 077840	Ondansetron Hydrochloride Injection, Equivalent to (EQ) 2 mg base/milliliters (mL).	Hospira, Inc., 275 N Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 077988	Fluconazole in Dextrose 5% Injection, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL).	Woodward Pharma Services LLC, 47220 Cartier Dr., Wixom, MI 48393.

Application No.	Drug	Applicant
ANDA 203265	Lidocaine Patch, 5%	Noven Pharmaceuticals, Inc., 11960 SW 144th St., Miami, FL 33186.
ANDA 203967	Escitalopram Oxalate Solution, EQ 5 mg base/5 mL	Antrim Pharmaceuticals LLC, 655 W Northcroft Ct., Lake Forest, IL 60045.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 3, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 3, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-26170 Filed 12-1-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tropical Disease Priority Review Vouchers

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 Tropical Disease Priority Review Vouchers.

DATES: Submit either electronic or written comments on the collection of information by January 31, 2022.

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 January 31, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 31, 2022. 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-2008-D-0530 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Tropical Disease Priority Review Vouchers." 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, 240-402-7500.

- **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