

B. Purpose

Firms performing under Federal contracts must provide adequate documentation to support requests for payment under these contracts. The documentation may range from a simple invoice to detailed cost data. The information is usually submitted once, at the end of the contract period or upon delivery of the supplies or services, but could be submitted more often depending on the payment schedule established under the contract (see Federal Acquisition Regulation (FAR) 52.232-1 through FAR 52.232-4, FAR 52.232-6, 52.232-7, and 52.232-10).

C. Annual Reporting Burden

Respondents: 1,724,163.

Responses per Respondent: 6.

Annual Responses: 10,344,978.

Hours per Response: 0.25.

Total Burden Hours: 2,586,245.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, at 202-501-4755. Please cite

OMB Control No. 9000-0070, Payments, in all correspondence.

Dated: April 15, 2019.

Janet Fry,

*Director, Federal Acquisition Policy Division,
Office of Governmentwide Acquisition Policy,
Office of Acquisition Policy, Office of
Governmentwide Policy.*

[FR Doc. 2019-07816 Filed 4-17-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1020]

Aurolife Pharma, LLC, et al.; Withdrawal of Approval of 31 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 31 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 20, 2019.

FOR FURTHER INFORMATION CONTACT:

Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@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 070470	Disopyramide Phosphate Capsules USP, Equivalent to (EQ) 100 milligrams (mg) base.	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 070471	Disopyramide Phosphate Capsules USP, EQ 150 mg base	Do.
ANDA 070531	Clofibrate Capsules USP, 500 mg	Upsher-Smith Laboratories, LLC, 301 South Cherokee St., Denver, CO 80223.
ANDA 070797	Chlorpheniramine Maleate Extended-Release Capsules USP, 12 mg	Aurolife Pharma, LLC.
ANDA 070956	Diazepam Tablets USP, 10 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 071128	Haloperidol Tablets USP, 0.5 mg	Cycle Pharmaceuticals, Ltd., c/o Mapi USA, Inc., 2343 Alexandria Dr., Suite 100, Lexington, KY 40504.
ANDA 071129	Haloperidol Tablets USP, 1 mg	Do.
ANDA 071133	Haloperidol Tablets USP, 20 mg	Do.
ANDA 072394	Fenoprofen Calcium Capsules USP, EQ 200 mg base	Aurolife Pharma, LLC.
ANDA 072395	Fenoprofen Calcium Capsules USP, EQ 300 mg base	Do.
ANDA 072396	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072484	Trazodone Hydrochloride (HCl) Tablets USP, 50 mg	Do.
ANDA 074024	Ketoprofen Capsules, 50 mg and 75 mg	Do.
ANDA 074448	Flurbiprofen Tablets USP, 50 mg and 100 mg	Do.
ANDA 078300	Pamidronate Disodium for Injection USP, 30 mg/vial and 90 mg/vial ..	Mustafa Nevzat Ilac San. A.S. (MN Pharmaceuticals), c/o Sagent Pharmaceuticals, Inc., 1901 North Roselle Rd., suite 450, Schaumburg, IL 60195.
ANDA 080655	Meprobamate Tablets USP, 400 mg	Aurolife Pharma, LLC.
ANDA 083234	Glutethimide Tablets, 500 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr. North, Maple Grove, MN 55369.
ANDA 084156	Pentobarbital Sodium Capsules, 100 mg	Warner-Lambert Company, 201 Tabor Rd., Morris Plains, NJ 07950.
ANDA 084674	Aminophylline Tablets USP, 100 mg	Halsey Drug Co., Inc.
ANDA 085628	Sulfisoxazole Tablets USP, 500 mg	Aurolife Pharma, LLC.
ANDA 085813	Prednisone Tablets USP, 20 mg	Do.
ANDA 085844	Sulfamethoxazole Tablets USP, 500 mg	Do.
ANDA 085925	Amitriptyline HCl Tablets USP, 50 mg	Halsey Drug Co., Inc.
ANDA 085926	Amitriptyline HCl Tablets USP, 75 mg	Do.
ANDA 085927	Amitriptyline HCl Tablets USP, 100 mg	Do.
ANDA 089057	Cyproheptadine HCl Tablets USP, 4 mg	Do.
ANDA 089117	Hydroxyzine HCl Tablets USP, 25 mg	Do.
ANDA 089894	Quinidine Gluconate Extended-Release Tablets USP, 324 mg	Aurolife Pharma, LLC.
ANDA 089983	Prednisone Tablets USP, 10 mg	Do.

Application No.	Drug	Applicant
ANDA 089984	Prednisone Tablets USP, 50 mg	Do. Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., suite 201, Berlin, CT 06037.
ANDA 208991	Piroxicam Capsules USP, 10 mg and 20 mg	

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 20, 2019. Approval of each entire application is withdrawn, including any strengths or products 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 May 20, 2019 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: April 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1517]

Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications

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 the information collection provisions of abbreviated new animal drug applications.

DATES: Submit either electronic or written comments on the collection of information by June 17, 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 June 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 17, 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-2019-N-1517 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications." 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.gpo.gov/fdsys/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