

information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On November 7, 2018, the Center for Biologics Evaluation and Research's APAC will meet in open session to discuss the use of challenge studies in the clinical development of allergenic products for the diagnosis and treatment of allergy due to aeroallergens. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* On November 7, 2018, from 9 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 31, 2018. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on

or before October 23, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 24, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-3463]

**Aurolife Pharma, LLC, et al.;  
Withdrawal of Approval of Seven  
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 seven 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 October 26, 2018.

**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](mailto: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 072112 .....	Clorazepate Dipotassium Capsules, 3.75 milligrams (mg), 7.5 mg, and 15 mg.	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 074863 .....	Clemastine Fumarate Syrup, Equivalent to (EQ) 0.5 mg base/5 milliliters (mL).	Workhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 080925 .....	Isocaine 3% (mepivacaine hydrochloride (HCl)) Injection USP, 3%.	Septodont, Inc., c/o Arent Fox, LLP, 1717 K St. NW, Washington, DC 20006.
ANDA 084048 .....	Octocaine (lidocaine HCl and epinephrine) Injection USP, 2%; 0.01 mg/mL and 2%; 0.02 mg/mL.	Do.
ANDA 084697 .....	Isocaine 2% (mepivacaine HCl and levonordefrin) Injection USP, 2%; 0.05 mg/mL.	Do.
ANDA 086033 .....	Isosorbide Dinitrate Sublingual Tablets USP, 2.5 mg ....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087504 .....	Chloroquine Phosphate Tablets USP, EQ 150 mg base	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Therefore, approval of the applications listed in the table, and all

amendments and supplements thereto, is hereby withdrawn as of October 26,

2018. 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 October 26, 2018 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: September 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0007]

#### Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2019

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2019 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2019.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's website at <https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>, or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6888, [Lisa.Kable@fda.hhs.gov](mailto:Lisa.Kable@fda.hhs.gov). For general questions, you may also email the Center for Veterinary Medicine (CVM) at [cvmagdufa@fda.hhs.gov](mailto:cvmagdufa@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j-21) establishes three different types of user fees: (1) Fees for

certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j-21(d)).

For FY 2019 through FY 2023, the FD&C Act establishes a yearly base revenue amount and percentages for each of these fee categories (21 U.S.C. 379j-21(b)). Base revenue amounts established for fiscal years after FY 2019 are subject to adjustment for inflation and workload. Workload increases will be adjusted for excess collections after FY 2020 (21 U.S.C. 379j-21(c)). The target revenue amounts for each fee category for FY 2019, are as follows: For application fees, the target revenue amount is \$4,584,000; for product fees, the target revenue amount is \$6,876,000; and for sponsor fees, the target revenue amount is \$6,876,000.

For FY 2019, the generic new animal drug user fee rates are: \$424,444 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$212,222 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); \$15,486 for each generic new animal drug product; \$150,098 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$112,574 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$75,049 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2019 product and sponsor fees by December 31, 2018. These fees will be due by January 31, 2019. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2018, and will remain in effect through September 30, 2019. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

##### II. Revenue Amount for FY 2019

###### A. Statutory Fee Revenue Amounts

AGDUFA III, Title II of Public Law 115-234, specifies that the aggregate revenue amount for FY 2019 for all generic new animal drug user fee categories is \$18,336,000 (rounded to the nearest thousand dollars) (21 U.S.C. 379j-21(b)(1)).

###### B. Inflation Adjustment to Fee Revenue Amount

AGDUFA III specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see 21 U.S.C. 379j-21(c)(2)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years. The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs. Because the adjustment for inflation does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for inflation.

###### C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j-21(c)(3)).

AGDUFA III specifies that FDA shall calculate the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions). Because the