4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2377]

Bayer HealthCare Pharmaceuticals, Inc., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three new drug applications (NDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process 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.

Table 1.--NDAs for Which Approval is Withdrawn

Application No.	Drug	Applicant
NDA 019857	Cipro in Dextrose 5% in Plastic Container (ciprofloxacin) Injectable, 200 milligrams (mg)/100 milliliters (mL) and 400 mg/200 mL	Bayer HealthCare Pharmaceuticals, Inc., 100 Bayer Blvd., Whippany, NJ 07981
NDA 021158	Factive (gemifloxacin mesylate) Tablet, Equivalent to (EQ) 320 mg base	LG Chem Ltd., C/O Parexel International, 2520 Meridian Parkway, Suite 200, Durham, NC 27713
NDA 021473	Cipro XR (ciprofloxacin hydrochloride) Extended-Release Tablet, EQ 287.5 mg base	Bayer HealthCare Pharmaceuticals, Inc.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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: May 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-11721 Filed: 5/28/2024 8:45 am; Publication Date: 5/29/2024]