4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1180]

Bayer HealthCare Pharmaceuticals Inc.; Withdrawal of Approval of New Drug Application for ALIQOPA (Copanlisib) for Injection, 60 Milligrams per Vial

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for ALIQOPA (copanlisib) for injection, 60 milligrams (mg)/vial, held by Bayer HealthCare Pharmaceuticals Inc., 100 Bayer Blvd., Whippany, NJ 07981-0915. Bayer HealthCare Pharmaceuticals Inc. (Bayer) has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: On September 14, 2017, FDA approved NDA 209936 for ALIQOPA (copanlisib) for injection, 60 mg/vial, for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of ALIQOPA (copanlisib) for injection, 60 mg/vial, for FL included required postmarketing trials intended to verify the clinical benefit of ALIQOPA.

FDA met with Bayer on November 8, 2023, to discuss voluntary withdrawal of ALIQOPA (copanlisib) for injection, 60 mg/vial, in accordance with § 314.150(d) (21 CFR

314.150(d)) because the required postmarketing trial did not verify the clinical benefit of copanlisib for FL.

On December 8, 2023, Bayer submitted a letter asking FDA to withdraw approval of NDA 209936 for ALIQOPA (copanlisib) for injection, 60 mg/vial, in accordance with § 314.150(d) and waiving its opportunity for a hearing. On December 11, 2023, FDA acknowledged Bayer's request for withdrawal of approval of the NDA and waiver of its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 209936 for ALIQOPA (copanlisib) for injection, 60 mg/vial, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of ALIQOPA (copanlisib) for injection, 60 mg/vial, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: March 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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