FOR FURTHER INFORMATION CONTACT: Amy Simms, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0648, *Amy.Simms@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #285 entitled ''Manufacture of Batches in Support of Original NADAs, ANADAs, and CNADAs.'' New animal drugs cannot be legally marketed unless they are the subject of an approved NADA, ANADA, or CNADA. The Chemistry, Manufacturing, and Controls (CMC) technical section is one portion of the original ANADA or CNADA and must contain full information regarding the manufacture of the new animal drug substance and new animal drug product. Animal drug manufacturing processes must be robust and able to produce drug product batches of consistent identity, strength, quality, and purity. Primary batches of drug product are manufactured as part of the original application. Data from these batches are used to establish that the manufacturing, sampling, and control processes described in the CMC portion of the application will consistently provide a quality, stable drug product that, within a batch and on a batch-to-batch basis, does not vary beyond the established specification(s). Additionally, they are used in studies to establish that the drug product is safe and effective (or in the case of an ANADA, bioequivalent to the reference listed new animal drug). As such, the primary batches demonstrate that the applicant can consistently manufacture batches of same quality as those used in safety and effectiveness (or bioequivalence) studies. This guidance provides recommendations for the primary batches of drug product manufactured to support the approval or conditional approval of new animal drug products.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Manufacture of Batches in Support of Original NADAs, ANADAs, and CNADAs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR 511.1 have been approved under OMB control number 0910–0117; and the collections of information in sections 512(b) and 512(n) of the Federal Food, Drug, and Cosmetic Act have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: March 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05686 Filed 3–15–24; 8:45 am]

BILLING CODE 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 March 18, 2024.

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.

[FR Doc. 2024–05619 Filed 3–15–24; 8:45 am]

BILLING CODE 4164–01–P