Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501–3521). The collections of information in 21 CFR 201.57 pertaining to certain prescription drug labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 312 pertaining to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

Dated: March 12, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–05683 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–D–1054]**

### Manufacture of Batches in Support of Original New Animal Drug Applications, Abbreviated New Animal Drug Applications, and Conditional New Animal Drug Applications; Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #285 entitled ''Manufacture of Batches in Support of Original NADAs, ANADAs, and CNADAs.'' This draft guidance is intended to provide recommendations for the primary batches of drug product manufactured to support the approval or conditional approval of new animal drug products. This guidance is applicable to all original new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs), and their associated investigational new animal drug files (INADs) and generic investigational new animal drug files, respectively, as well as applications for conditional approval of new animal drugs (CNADAs).

**DATES:** Submit either electronic or written comments on the draft guidance by May 17, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*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–2024–D–1054 for ''Manufacture of Batches in Support of Original NADAs, ANADAs, and CNADAs.'' Received comments 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, 240–402–7500.

- 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.govinfo.gov/content/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 ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**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**