www.regulations.gov. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

*1. Sullivan, H.W., K.J. Aikin, and L.B. Squiers, ''Quantitative Information on Oncology Prescription Drug websites,'' *Journal of Cancer Education,* vol. 33, Issue 2, pp. 371–374, 2018. (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5334459*)

2. Dillman, D.A., J.D. Smyth, and L.M. Christian, *internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method, 4th ed.,* John Wiley & Sons, Inc.: Hoboken, NJ, 2014.

*3. Cheung, Y.T.D., X. Weng, M.P. Wang, et al., ''Effect of Prepaid and Promised Financial Incentive on Follow-Up Survey Response in Cigarette Smokers: A Randomized Controlled Trial,'' *BMC Medical Research Methodology,* vol. 19, Article 138, 2019. (*https://link.springer.com/article/10.1186/s12874-019-0786-9*)

4. Mercer, A., A. Caporaso, D. Cantor, et al., ''How Much Gets You How Much? Monetary Incentives and Response Rates in Household Surveys,'' *Public Opinion Quarterly,* vol. 79, pp. 105–129, 2015.

5. Sun, H., J. Newsome, J. McNulty, et al., ''What Works, What Doesn't? Three Studies Designed to Improve Survey Response,'' *Field Methods,* vol. 32, Issue 3, pp. 235–252, 2020. (*https://doi.org/10.1177/1525822X20915464*)

6. Ellis, J., J. Charbonnier, C. Lowenstein, et al., ''Assessing the Impacts of Different Incentives and Use of Postal Mail on Response Rates,'' *American Association for Public Opinion Research (AAPOR) Conference,* Chicago, IL, 2022, May.

*7. Yu, S., H.E. Alper, A.M. Nguyen, et al., ''The Effectiveness of a Monetary Incentive Offer on Survey Response Rates and Response Completeness in a Longitudinal Study,'' *BMC Medical Research Methodology,* vol. 17, Article 77, 2017. (*https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-017-0353-1*)

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27652 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5323]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of Two New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of two 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 January 17, 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: 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 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 under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 021455	Boniva (ibandronate sodium) Tablets, equivalent to (EQ) 2.5 milligrams (mg) base and EQ 150 mg base.	Hoffmann-La Roche, Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080–4990.
NDA 022424	Flowtuss (guaifenesin 200 mg/5 milliliters (mL) and hydrocodone bitartrate 2.5 mg/5 mL) Oral Solution.	Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 17, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table 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 the table that are in inventory on January 17, 2024 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: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27661 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3740]

Priority Zoonotic Animal Drug Designation and Review Process; 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) #283 entitled ''Priority Zoonotic Animal Drug Designation and Review Process.'' This draft guidance is intended to assist sponsors pursuing priority zoonotic animal drug (PZAD) designation for a new animal drug. This draft guidance is intended to provide the eligibility criteria for PZAD designation, the process for requesting PZAD designation, and enhancements in the FDA review process for PZADs.

DATES: Submit either electronic or written comments on the draft guidance by February 16, 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–2023–D–3740 for ''Priority Zoonotic Animal Drug Designation and Review Process.'' 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: Evgenij Evdokimov, Center for Veterinary Medicine (HFV–108), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0712, *evgenij.evdokimov@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #283 entitled ''Priority Zoonotic Animal Drug Designation and Review Process.'' The Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116–136), signed into law on March 27, 2020, added section 512A ''Priority zoonotic animal drugs'' to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b–1), which provides for the designation of a new animal drug as a PZAD. This legislation is intended to expedite the development and review of certain new animal drugs that have the potential to prevent or treat a zoonotic disease in animals, including a vector-borne disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

This draft guidance is intended to assist sponsors pursuing designation of a new animal drug as a PZAD. This draft guidance proposes the eligibility criteria a new animal drug should meet to obtain PZAD designation and describes the process sponsors may use to request such designation. In addition, this draft guidance identifies the enhancements FDA intends to implement to expedite the PZAD review process.

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 ''Priority Zoonotic Animal Drug Designation and Review Process.'' 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 514 have been approved under OMB control number 0910–0032; 21 CFR 511.1 have been approved under OMB control number 0910–0117.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27655 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5344]

Pharmacyclics LLC.; Withdrawal of Approval of Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma for IMBRUVICA (ibrutinib) Capsules and Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for mantle cell lymphoma (MCL) and marginal zone lymphoma (MZL) for IMBRUVICA (ibrutinib) Capsules and Tablets approved, respectively, under new drug applications (NDAs) 205552 and 210563. These NDAs are held by Pharmacyclics LLC, 1000 Gateway Blvd., South San Francisco, CA 94080 (Pharmacyclics). Pharmacyclics voluntarily requested that the Agency withdraw approval of these indications and waived its opportunity for a hearing.

DATES: Approval is withdrawn as of December 18, 2023.

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 November 13, 2013, FDA approved NDA 205552 for IMBRUVICA (ibrutinib) Capsules for the treatment of adult patients with MCL who have received at least one prior therapy (the MCL indication). On January 18, 2017, FDA approved a prior approval supplement for NDA 205552 for IMBRUVICA (ibrutinib) Capsules for the treatment of adult patients with MZL who require systemic therapy and have received at least one prior anti-CD20-based therapy (the MZL indication). On February 16, 2018, FDA approved NDA 210563 for IMBRUVICA (ibrutinib) Tablets, a new dosage form of IMBRUVICA (ibrutinib), for the MCL and MZL indications. FDA approved the MCL and MZL indications for both products under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of IMBRUVICA (ibrutinib) Capsules and Tablets for the MCL and MZL indications, the applicant was required to conduct postmarketing trials to verify the clinical benefit of ibrutinib for the MCL and MZL indications.

On February 8, 2023, FDA met with Pharmacyclics to inform the applicant of the plans to convene the Oncologic Drugs Advisory Committee regarding the accelerated approvals for the MCL and MZL indications because the required postmarketing trials did not verify the clinical benefit of ibrutinib for these indications. On March 21, 2023, FDA met with Pharmacyclics to discuss the applicant's request to voluntarily withdraw approval of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets. On April 6, 2023, Pharmacyclics submitted a letter requesting withdrawal of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing.

Therefore, under § 314.150(d), approvals of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets are withdrawn as of December 18, 2023. Withdrawal of approval of these indications does not affect any other approved indication for IMBRUVICA (ibrutinib) Capsules and Tablets.

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27662 Filed 12–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Funding Opportunity for the Community Opioid Intervention Prevention Program

Announcement Type: New.

Funding Announcement Number: HHS–2024–IHS–COIPP–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: February 7, 2024.

Earliest Anticipated Start Date: April 1, 2024.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), Office of Clinical and Preventive Services, Division of Behavioral Health (DBH) is accepting applications for grants for the Community Opioid Intervention Prevention Program (COIPP). This program is authorized under the Snyder Act, 25 U.S.C. 13, and the Transfer Act, 42 U.S.C. 2001(a). Funding for this program is provided in the Consolidated Appropriations Act, 2023, Public Law 117–328, 136 Stat. 4459, 4808 (2022). The Assistance Listings section of *SAM.gov* (*https://sam.gov/content/home*) describes this program under 93.654.

Background

The initial opioid prevention program, called the Community Opioid Intervention Pilot Project, was first established in Fiscal Year (FY) 2019, pursuant to Congressional instruction to better combat the opioid epidemic. The goal was to create a pilot program to address the opioid epidemic in Indian Country and award grants that supported the development, documentation, and sharing of locally designed and culturally appropriate prevention, treatment, recovery, and aftercare services for opioid use disorders in the American Indian and Alaska Native (AI/AN) communities. Evidence-based activities are available for reference at *https://www.ihs.gov/asap/coipp/.* A total of 35 grants were awarded to Tribal and Urban Indian communities in the pilot phase. Based on evaluation results from the pilot project, this funding opportunity will continue to provide grant support to Tribal and Urban Indian communities to continue efforts to combat the opioid epidemic and develop strategies that align with the Department of Health and Human Services Overdose Prevention Strategy.

The Centers for Disease Control and Prevention (CDC) reported that the AI/AN population had the highest drug overdose death rates in both 2020 and 2021, at rates of 42.5 and 56.6 deaths per 100,000 persons, respectively. The AI/AN population also experienced a 33 percent increase in drug overdose deaths from 2020 through 2021. Overdose deaths among AI/AN have continued to increase over the last 20 years. The CDC reported from 2019 to 2020, overdose death rates increased 39 percent for the non-Hispanic AI/AN population and drug overdose death rates were highest for AI/AN people compared to other racial and ethnic groups.