Dated: March 9, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–05371 Filed 3–15–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–N–0212]**

### Bristol-Meyers Squibb Company, et al.; Withdrawal of Approval of 19 New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 19 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of April 15, 2021.

**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 or abbreviated application under § 314.150(c) is without prejudice to refiling.

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 009218 ..... | Coumadin (warfarin sodium) Tablets, 1 milligram (mg), 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, and 10 mg. Coumadin (warfarin sodium) Injection, 5 mg/vial, 50 mg/vial, and 75 mg/vial. | Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543. |
| NDA 011664 ..... | Decadron (dexamethasone) Tablets, 0.25 mg, 0.5 mg, 0.75 mg, 1.5 mg, 4 mg, and 6 mg. | Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., 1 Merck Dr., Whitehouse Station, NJ 08889. |
| NDA 017481 ..... | Vermox (mebendazole) Chewable Tablets, 100 mg ..... | Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560. |
| NDA 018538 ..... | Lozol (indapamide) Tablets, 1.25 mg, and 2.5 mg ..... | Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807. |
| NDA 018986 ..... | Pralidoxime Chloride Injection (auto-injector), 600 mg/2 milliliters (mL) (300 mg/mL). | Meridian Medical Technologies, Inc., 1945 Craig Rd., St. Louis, MO 63146. |
| NDA 019999 ..... | Morphine Sulfate Injection (auto-injector), 10 mg/0.7 mL ..... | Do. |
| NDA 020363 ..... | Famvir (famciclovir) Tablets, 125 mg, 250 mg, and 500 mg ... | Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936–1080. |
| NDA 020711 ..... | Zyban (bupropion hydrochloride (HCl)) Extended-Release Tablets, 100 mg, and 150 mg. | GlaxoSmithKline LLC, 5 Crescent Dr., Philadelphia, PA 19112. |
| NDA 020809 ..... | Diclofenac Sodium Ophthalmic Solution, 0.1% ..... | Alcon Research, LLC, 6201 South Freeway, Fort Worth, TX 76134. |
| NDA 021713 ..... | Abilify (aripiprazole) Oral Solution, 1 mg/mL ..... | Otsuka Pharmaceutical Co., Ltd. c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850. |
| NDA 021729 ..... | Abilify (aripiprazole) Discmelt Orally Disintegrating Tablets, 10 mg, 15 mg, 20 mg, and 30 mg. | Do. |
| NDA 021866 ..... | Abilify (aripiprazole) Injection, 9.75 mg/1.3 mL (7.5 mg/mL) ... | Do. |
| NDA 022024 ..... | Actoplus Met XR (metformin HCl and pioglitazone) Extended-Release Tablets, 1gram (g)/Equivalent to (EQ) 15 mg base and 1 g/EQ 30 mg base. | Takeda Pharmaceutical U.S.A. Inc., 95 Hayden Ave., Lexington, MA 02421. |
| NDA 050605 ..... | Ceftin (cefuroxime axetil) Tablets, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base. | GlaxoSmithKline Intellectual Property (no. 2) Ltd. England, c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426. |
| NDA 050672 ..... | Ceftin (cefuroxime axetil) Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL. | Do. |
| NDA 207988 ..... | Zurampic (lesinurad) Tablets, 200mg ..... | Ironwood Pharmaceuticals, Inc., 100 Summer St., Suite 2300, Boston MA 02110. |
| NDA 208383 ..... | Bevyxxa (betrixaban) Capsules, 40 mg and 80 mg ..... | Portola Pharmaceuticals, Inc., 270 East Grand Ave., South San Francisco, CA 94080. |
| NDA 210709 ..... | Tekturna (aliskiren hemifumarate) Capsules (Pellets), EQ 37.5 mg base. | Nodem Pharma DAC, 4820 Emperor Blvd., Durham, NC 27703. |
| NDA 210874 ..... | Qternmet XR (dapagliflozin, metformin HCl and saxagliptin) Extended-Release Tablets, 2.5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 5 mg base, and 10 mg/1 g/EQ 5 mg base. | AstraZeneca AB, c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 15, 2021. 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 without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table

that are in inventory on April 15, 2021 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: March 9, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–05368 Filed 3–15–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2002–N–0314]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the regulations that state that protocols for samples of biological products must be submitted to the Agency.

**DATES:** Submit either electronic or written comments on the collection of information by May 17, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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–2002–N–0314 for ''Request for Samples and Protocols.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice