

expiration date. The new charter will be in effect until August 27, 2022.

**DATES:** Authority for the Cardiovascular and Renal Drugs Advisory Committee will expire on August 27, 2022, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Joyce Yu, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993-0002, 301-796-9001, email: [CRDAC@fda.hhs.gov](mailto:CRDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under 41 CFR 102-3, FDA is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee (Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

Under its Charter, the Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. There may also be alternate industry representative.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/cardiorenal-drugs-advisory-committee/cardiorenal-drugs-advisory-committee-charter> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**).

In light of the fact that no change has been made to the Committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: September 18, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1227]

#### Roerig Division of Pfizer Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on July 21, 2020. The document announced the withdrawal of approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 20, 2020. The document indicated that FDA was withdrawing approval of the following two ANDAs after receiving a withdrawal request from Kadmon Pharmaceuticals, LLC., 119 Commonwealth Dr., Warrendale, PA 15086: ANDA 076203, Ribavirin Capsules, 200 milligrams (mg) and ANDA 077456, Ribavirin Tablets, 200 mg, 400 mg, and 600 mg. Before FDA withdrew the approval of these ANDAs, Kadmon Pharmaceuticals, LLC. informed FDA that it did not want the approval of the ANDAs withdrawn. Because Kadmon Pharmaceuticals, LLC., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 076203 and 077456 are still in effect.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Correction**

In the **Federal Register** of Tuesday, July 21, 2020 (85 FR 44096), appearing on page 44096 in FR Doc. 2020-15727, the following correction is made:

On page 44096, in the table, the entries for ANDAs 076203 and 077456 are removed.

Dated: September 21, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-1445]

#### Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use." This guidance describes studies and information that FDA recommends be used when submitting premarket notifications (510(k)s) for blood glucose monitoring systems (BGMSs) that are for prescription point-of-care use.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 29, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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