21 CFR part; guidance; or FDA form	Topic	OMB control No.
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
830	Unique Device Identification System	0910–0720
820	Quality System Regulation	0910–0073

Dated: September 24, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21453 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1787]

Advisory Committee; Blood Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2022, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054 *Christina.Vert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Blood Products Advisory Committee advises 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 shall consist of a core of 17 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. 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. 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.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm121602.htm* 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 visit us at *https://www.fda.gov/advisory-committees.*

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21454 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3091]

Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cardiovascular and Renal Drugs Advisory Committee for an additional 2 years beyond the charter

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.*

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/cardiovascular-and-renal-drugs-advisory-committee/cardiovascular-and-renal-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.

[FR Doc. 2020–21465 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

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.*

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.

[FR Doc. 2020–21456 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

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