



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: 9/28/2020 8:45 am; Publication Date: 9/29/2020]