



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5888]

Advisory Committee; Pharmaceutical Science and Clinical Pharmacology Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology 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 Pharmaceutical Science and Clinical Pharmacology Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until January 22, 2022.

DATES: Authority for the Pharmaceutical Science and Clinical Pharmacology Advisory Committee will expire on January 22, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jay Fajiculay, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: ACPS-CP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The

committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Pharmaceutical Science and Clinical Pharmacology 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 reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner. The committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

Pursuant to its Charter, the Pharmaceutical Science and Clinical Pharmacology Advisory Committee shall consist of a core of 14 voting members including two Chairpersons. Members and Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, and microbiology) and clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations, and innovative methods in drug development), biostatistics, related biomedical and pharmacological specialties,

current good manufacturing practices, and quality systems implementation. 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 up to three non-voting members who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/human-drug-advisory-committees/pharmaceutical-science-and-clinical-pharmacology-advisory-committee> 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: December 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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