II. Topics for Discussion at the Public Meeting

FDA Center Directors will hold a panel discussion on pressing FDA initiatives suitable for Public-Private Partnerships. Panelists will include Drs. Janet Woodcock, Peter Marks, and Jeffrey Shuren. The panel moderator will be Michael McCaughan, Co-Founder of Prevision Policy. Find the meeting page at *http://reaganudall.org/2019-annual-public-meeting-0.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://reaganudall.salsalabs.org/2019AnnualMeeting/index.html.* Persons interested in attending this public meeting must register online by April 30, 2019, at 5 p.m. Eastern Time.

If you need special accommodations due to a disability, please contact Kelly Catterton (see **FOR FURTHER INFORMATION CONTACT**) no later than April 30, 2019, at 5 p.m. Eastern Time.

Requests for Oral Presentations: Interested persons may present comments at the public meeting. Comments will be scheduled to begin approximately at 11:45 a.m. Time allotted for comments is limited to 3 minutes per speaker. Those desiring to make oral comments should notify Kelly Catterton (see **FOR FURTHER INFORMATION CONTACT**) by April 30, 2019, at 5 p.m. Eastern Time. Please include a brief statement of the general nature of the comments you wish to present along with your name, address, telephone number, and email address. The contact person will notify individuals regarding their request to speak by May 1, 2019.

Dated: March 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–05944 Filed 3–27–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0428]

Advisory Committee; Cellular, Tissue and Gene Therapies 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 Cellular, Tissue and Gene Therapies Advisory Committee (Committee) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until October 28, 2020.

DATES: Authority for the Cellular, Tissue and Gene Therapies Advisory Committee will expire on October 28, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993; 240–402–8006, email: *Prabhakara.atreya@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 Committee. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The 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 available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of thirteen voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies, and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics). Members will be invited to serve for overlapping terms of up to four 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.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/default.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/AdvisoryCommittees/default.htm.*

Dated: March 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–05985 Filed 3–27–19; 8:45 am]

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