address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10305 Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g); *Use:* The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR 422.516(a) and 423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data. In order for the reported data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation. Sponsoring organizations are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials, which CMS outlines in the ''Standards for Selecting Data Validation Contractors'' document. For the retrospective review in 2020, the DVCs will review data submitted by sponsoring organizations for CY2019. *Form Number:* CMS–10305 (OMB control number: 0938–1115); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 553; *Total Annual Responses:* 553; *Total Annual Hours:* 15,332. (For policy questions regarding this collection contact Maria Sotirelis at 410–786–0552.)

Dated: March 25, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–05978 Filed 3–27–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1131]

Annual Public Meeting; Reagan-Udall Foundation for the Food and Drug Administration

AGENCY: Reagan-Udall Foundation, FDA, HHS.

ACTION: Notice of annual meeting.

SUMMARY: The Reagan-Udall Foundation (the Foundation) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public meeting. The Foundation will discuss its activities and how they support FDA.

DATES: The public meeting will be held on May 2, 2019, from 10 a.m. until 12 noon. Registration to attend the meeting must be received by April 30, 2019, at 5 p.m. Eastern Time. Requests for oral presentation must be received before April 30, 2019, at 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. The public is also invited to submit written comments by sending them via email to Kelly Catterton (see **FOR FURTHER INFORMATION CONTACT**) before April 30, 2019, at 5 p.m. Eastern Time.

ADDRESSES: The public meeting will be held at the PEW Charitable Trusts, 901 E St. NW, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Kelly Catterton, Executive Assistant to the Executive Director, Reagan-Udall Foundation for FDA, 202–849–2255, *kcatterton@reaganudall.org.*

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit, organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation, and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research and engagement projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how the Foundation projects can help the Agency to fulfill its mission.

Foundation projects currently include: Innovation in Medical Evidence Development and Surveillance, a public-private partnership that allows researchers to study drug safety concerns of interest to public health; an Expanded Access Navigator that offers instructional material and resources for physicians, patients, and their caregivers on how to access investigational drugs outside of clinical trials; and a new joint Foundation and FDA regulatory science fellowship program.

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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4164–01–P