DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1533; FDA–2019–N–2313; FDA–2013–N–0825; FDA–2013–N–1427; FDA–2013–N–1393; FDA–2013–N–0719; FDA–2013–N–0796; and FDA–2018–D–4711]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
National Panel of Tobacco Consumer Studies	0910–0815	2/28/2023
Study of Oncology Indications in Direct-to-Consumer Television Advertising	0910–0885	2/28/2023
Premarket Approval of Medical Devices	0910–0231	3/31/2023
Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing of Juice	0910–0466	3/31/2023
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	4/30/2023
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	0910–0675	4/30/2023
Testing Communications on Medical Devices and Radiation-Emitting Products	0910–0678	4/30/2023
Requests for Nonbinding Feedback After Certain FDA Inspections of Device Establishments	0910–0886	4/30/2023

Dated: May 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10977 Filed 5–20–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1291]

Stakeholder Engagement on ICH E6: Guideline for Good Clinical Practice; Public Web Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public web conference.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a free public web conference for discussion of the International Council for Harmonisation's (ICH's) good clinical practice guidelines, ICH E6. This public web conference, ''Stakeholder Engagement on ICH E6: Guideline for Good Clinical Practice,'' is being convened and supported by a cooperative agreement between the Clinical Trials Transformation Initiative (CTTI) and FDA. The purpose of the web conference is to capture stakeholder experiences with current ICH E6 guidelines for good clinical practice (GCP) and to gather stakeholder input to further inform the development of an updated guideline, ICH E6(R3).

DATES: The public web conference will be held on Thursday and Friday, June 4 and 5, 2020, from 10 a.m. to 1 p.m. Eastern Time. Further details on the web conference (including times) are available at the website provided under **ADDRESSES**. See the **SUPPLEMENTARY INFORMATION** section for details.

ADDRESSES: The web conference will be held online. Meeting details and background materials, including the web conference link, are available at the following website: *https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.*

FOR FURTHER INFORMATION CONTACT: Suzanne Pattee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3328, Silver Spring, MD 20993, 301–796–1706, *Suzanne.Pattee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

To support GCP renovation, FDA and ICH are seeking stakeholder input to develop a new ICH guideline, ''ICH E6(R3): Guideline for Good Clinical Practice,'' to enable flexible application of those guidelines to interventional clinical trials, including innovative clinical trial designs and data sources. ICH E6(R3) materials, including the ICH Reflection Paper on ''GCP Renovation,'' concept paper, business plan, work plan, and an expert list, as well as the current guideline, ''ICH E6(R2): Guideline for Good Clinical Practice,'' are available on the ICH website: *https://www.ich.org/page/efficacy-guidelines.*

The purpose of the public web conference announced in this notice is to obtain input on stakeholder experiences with the current GCP guideline (ICH E6(R2)) and suggested changes to improve the guideline's applicability to the changing clinical trial landscape.

II. Topics for Discussion at the Public Web Conference

During the public web conference, speakers and participants will cover a range of GCP issues to inform revisions to the current GCP guidelines. Topics for discussion will include and are not limited to: (1) Issues with application of current guidelines to traditional interventional clinical trials, (2) ways to modify the guideline to address innovative trial designs, (3) use of digital technology tools, (4) new data sources, and (5) other topics relating to GCPs.

III. Participating in the Public Web Conference

Registration: To register for the free public web conference, complete the registration form at *https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Streaming Public Web Conference: This live web conference will be recorded and archived and will be available after the event at the event website. Persons interested in participating in the live web conference are encouraged to register in advance (see *Registration*). The live web conference will also be available at the website above on the day of the event without preregistration. Detailed information is available at the following website: *https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.*

Registered web conference participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming web conference of the public event.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the web conference and will be publicly available at the *https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.*

Transcripts: Please be advised that transcripts of the public web conference will not be available.

Dated: May 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10975 Filed 5–20–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1242]

Advisory Committee; Arthritis 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 Arthritis 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 Arthritis Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until April 5, 2022.

DATES: Authority for the Arthritis Advisory Committee would have expired on April 5, 2020, unless the Commissioner had formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yinghua Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *AAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under 41 CFR 102–3, FDA is announcing the renewal of the Arthritis Advisory 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 data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, 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 arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties. 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 representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/arthritis-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/advisory-committees.*

Dated: May 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10996 Filed 5–20–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Clinical Care Commission

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Clinical Care Commission (the Commission) will conduct a virtual meeting on June 26, 2020. The Commission is charged to evaluate and make recommendations to the U.S. Department of Health and Human Services (HHS) Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to diabetes and its complications.

DATES: The meeting will take place on June 26, 2020, from 1 p.m. to approximately 5 p.m. Eastern Daylight time (EDT).