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.

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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.