DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1094]

2018 Center for Biologics Evaluation and Research Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public symposium.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public symposium entitled ''2018 Center for Biologics Evaluation and Research Science Symposium.'' The purpose of the public symposium is to discuss scientific topics related to the regulation of biologics and highlight science conducted at the Center for Biologics Evaluation and Research (CBER) by showcasing how scientific research informs regulatory decision making and to provide a forum for developing collaborations within FDA and with external organizations. The symposium will include presentations by experts from academic institutions, government agencies, and research institutions.

DATES: The public symposium will be held on June 25 and 26, 2018, from 9 a.m. to 3 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public symposium will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public symposium participants (non-FDA employees) is through Bldg. 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Sherri Revell or Loni Warren Henderson, Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8010, email: *CBERPublicEvents@fda.hhs.gov* (subject line: CBER Science Symposium).

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public symposium is to discuss scientific topics related to the regulation of biologics and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision making and to provide a forum for developing collaborations within FDA and with external organizations.

II. Topics for Discussion at the Public Symposium

The public symposium will include presentations on the following topics: (1) Emerging and re-emerging diseases; (2) diverse types of data in regulatory decision making; (3) immune response to vaccination; (4) immunotherapy; (5) new technologies for research and treatments; (6) the role of the microbiome in human disease; and (7) regenerative medicine.

III. Participating in the Public Symposium

Registration: To register for the public symposium, please visit the following website: *https://www.eventbrite.com/e/2018-center-for-biologics-evaluation-and-research-cber-science-symposium-tickets-39525851887.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public symposium (either in person or by webcast) (see *Streaming Webcast of the Public Symposium)* must register online by June 18, 2018, midnight Eastern Time. Early registration is recommended because seating is limited. There will be no onsite registration; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations, due to a disability, please contact Sherri Revell or Loni Warren Henderson no later than June 11, 2018.

Streaming Webcast of the Public Symposium: This public symposium will also be webcast. A link to the live webcast of this symposium will be provided upon registration at *https://www.eventbrite.com/e/2018-center-for-biologics-evaluation-and-research-cber-science-symposium-tickets-39525851887.* Persons interested in viewing the live webcast must register online by June 18, 2018. Early registration is recommended because webcast connections are limited. A video record of the public symposium will be available at *https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/default.htm* for 1 year.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* 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.

Dated: March 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1027; FDA–2017–N–1064; FDA–2014–D–0329; FDA–2013–N–1429; FDA–2009–N–0505; and FDA–2014–N–0192]

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 *https://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.