the technical requirements for the approval of pharmaceuticals for human use in the ICH regions since 1990. More information on the current ICH process and structure can be found at the following website: http://www.ich.org.

II. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by October 12, 2018. To register to attend the public meeting either in person or via webcast, please visit the following website: https://www.eventbrite.ca/e/health-canada-us-fda-ich-consultation-tickets-47713713000. 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 meeting must register by October 12, 2018, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, the number of participants from each organization may be limited. The agenda for the public meeting will be made available on the internet at https://www.fda.gov/Drugs/NewsEvents/ucm612657.htm approximately 2 weeks in advance of the meeting.

If you need special accommodations due to a disability, please contact William Lewallen (see FOR FURTHER INFORMATION CONTACT) no later than October 12, 2018.

Requests for Oral Presentations: If you wish to make a presentation during the public comment session, please contact William Lewallen (see FOR FURTHER INFORMATION CONTACT) no later than October 12, 2018. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make presentations must be received by the close of registration on October 12, 2018. If selected for presentation, any presentation materials must be emailed to William Lewallen (see FOR FURTHER INFORMATION CONTACT) no later than October 12, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. To register to attend via webcast, please visit the following website: https://www.eventbrite.ca/e/health-canada-us-fda-ich-consultation-tickets-47713713000. 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.


Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting Allergy, Immunology, and Transplantation Research Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Allergy, Immunology, and Transplantation Research Committee

Date: October 24, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892

(Daylight Conference Call).

Contact Person: Leslie Kux, Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting Allergy, Immunology, and Transplantation Research Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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(Conference Telephone Call).

Contact Person: Leslie Kux, Associate Commissioner for Policy.