4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0001]

Model Informed Drug Development Approaches for Immunogenicity Assessments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research, in collaboration with the Center for Drug Evaluation and Research, is announcing the following public workshop entitled "Model Informed Drug Development Approaches for Immunogenicity Assessments." The purpose of this public workshop is to discuss the best practices and future directions of quantitative methods for predicting immunogenicity of biological products. This public workshop is also being conducted to satisfy one of FDA's performance goals included in the sixth reauthorization of the Prescription Drug User Fee Amendments (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA), to hold a series of workshops related to model-informed drug development (MIDD).

DATES: The public workshop will be held virtually on June 9, 2021, from 8 a.m. to 5 p.m., Eastern Time. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID-19 pandemic, all participants will be joining this public workshop via an online teleconferencing platform. The public workshop will be held virtually via Adobe Connect. Webcast information will be provided upon completion of registration.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240-402-8010, CBERPublicEvents@fda.hhs.gov (subject line: MIDD Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA, and in accordance with section I, part J of the PDUFA VI Performance Goals, FDA agreed to convene a series of workshops to identify best practices for MIDD (https://www.fda.gov/media/99140/download, see page 27). Each workshop focuses on current and emerging scientific approaches, including methodological limitations. The workshop announced in this notice fulfills FDA's performance commitment under PDUFA VI, specifically for modeling immunogenicity and correlates of protection for evaluating biological products, including vaccines and blood products.

II. Topics for Discussion at the Public Workshop

Topics for discussion include the following:

1. Current in silico methodologies used to assess drug immunogenicity;
2. Available data resources and data needs for MIDD approaches to evaluate immunogenicity at various stages of drug development;
3. Possible applications and limitations of MIDD approaches for desired immunogenicity of vaccine/allergenic products; and
4. Insight into the possible future applications of MIDD and good modeling practices.

A detailed agenda will be posted in advance of the workshop at https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online by May 26, 2021, at https://www.eventbrite.com/e/model-informed-drug-development-approaches-for-immunogenicity-assessments-tickets-138618787525. 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.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell (see FOR FURTHER INFORMATION CONTACT) no later than May 26, 2021. Please note, Computer Aided Realtime Translation/captioning will be available.

Streaming Webcast of the Public Workshop: This public workshop will be streamed via webcast only.

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.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. A link to the transcript will also be available on the internet at https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics.

Dated: April 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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