4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4100]

Drug Development Tool Process under the 21st Century Cures Act and Prescription Drug User Fee Act VI; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public meeting entitled "Drug Development Tool Process under the 21st Century Cures Act and PDUFA VI." This public meeting is intended to fulfill commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI) and the 21st Century Cures Act (Cures Act) by soliciting comments on Drug Development Tool Qualification at FDA related to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act); discussing taxonomy for biomarkers and related concepts used in drug development; and planning activities to define a framework with appropriate standards and scientific approaches to support qualification for a specified context of use.

DATES: The public meeting will be held on December 11, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by January 31, 2019. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD, 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 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.

You may submit comments as follows. Please note that late, untimely filed comments may not be considered. For timely consideration we request that electronic comments be submitted on or before January 31, 2019. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time on January 31, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier: Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-4100 for "Drug Development Tools Qualification under the 21st Century Cures Act and PDUFA VI." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed

confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie Jimenez, Center for Drug Evaluation and Research, Food and Drug Administration, Hillandale Bldg., Rm. 2156, Silver Spring, MD 20993; 301-796-1345, QualificationPublicMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Development Tool (DDT) provisions in section 507 of the FD&C Act (21 U.S.C. 357) were added in December 2016 by section 3011 of the Cures Act (Pub. L. 114-255). FDA's DDT programs include the Animal Model Qualification Program, the Biomarker

Qualification Program, and the Clinical Outcome Assessment Qualification Program. These programs are designed to facilitate drug and biological product development by allowing FDA to qualify DDTs based on certain foundational scientific information, thereby minimizing duplication of research and development efforts. FDA committed to meet certain performance goals under PDUFA VI. This reauthorization, part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.6.b. of the commitment letter, "Enhancing Drug Development Tools Qualification Pathway for Biomarkers," states that FDA will convene a public meeting to discuss taxonomy for biomarkers used in drug development and a framework with appropriate standards and scientific approaches to support biomarkers under the taxonomy, including scientific criteria to determine acceptance of a biomarker qualification submission and essential elements of a formal biomarker qualification plan. Since there are overlapping deliverables between the Cures Act and PDUFA VI, this public meeting will address and fulfill those deliverables.

II. Topics for Discussion at the Public Meeting

FDA is convening a public meeting to discuss and seek public input regarding the DDT qualification pathway for animal models, biomarkers, and clinical outcome assessments. This public meeting will describe the qualification process under section 507 of the FD&C Act and will discuss taxonomy used in drug development, which will include the scientific criteria to

determine the acceptance of a qualification submission and essential elements of a full qualification plan. In addition, we will discuss ongoing activities to develop general evidentiary standards to support qualification by the three qualification programs.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: https://www.eventbrite.com/e/drug-development-tool-process-under-the-21st-century-cures-legislation-tickets-50528044742. 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 11:59 p.m. Eastern Time on Friday, November 30, 2018. Registrants will receive confirmation when they have been accepted. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact QualificationPublicMeeting@fda.hhs.gov no later than Friday, November 30, 2018, by 11:59 p.m. Eastern Time.

Requests for Oral Presentations: There will be time allotted during the public meeting for open public comment. Signup for this session will be on a first-come, first-served basis; there will be a time limit on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Webcast Information: FDA plans to provide a free, live webcast of this public meeting. The link to the public meeting is https://collaboration.fda.gov/r7zu2p7t3ab, which will not be accessible until 45 minutes prior to the meeting.

FDA plans to post archived webcasts after the meeting; archived webcasts will be available.

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 meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES).

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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