



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2769]

Development of New Tuberculosis Treatment Regimens--Scientific and Clinical Trial Design Considerations; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is/are announcing a public workshop regarding scientific and clinical trial design considerations for the development of new tuberculosis (TB) treatment regimens. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders regarding scientific and clinical trial design considerations related to the development of new TB regimens.

DATES: The public workshop will be held on July 19, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by August 1, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information. The workshop draft agenda will be made available at <https://www.fda.gov/Drugs/NewsEvents/ucm548365.htm> prior to the meeting.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop 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 will not be considered. Electronic comments must be submitted on or before August 1, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight eastern time on August 1, 2017. 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 (for written/paper submissions): 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-2017-N-2769 for "Development of New Tuberculosis Treatment Regimens--Scientific and Clinical Trial Design Considerations; Public Workshop; Request for Comments." 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: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding scientific and clinical trial design considerations for the development of new TB drug regimens. As such, discussions will focus

on drug development programs and studies intended to evaluate shorter and better tolerated TB drug regimens and new regimens that have efficacy for treatment of sensitive and drug-resistant TB.

II. Topics for Discussion at the Public Workshop

The FDA is conducting this workshop to focus on scientific considerations needed to advance the development of new TB treatment regimens. FDA is particularly interested in discussing pre-clinical and clinical considerations relevant to the development of new TB treatment regimens. Discussions are planned around the following topics:

- Current landscape and challenges in TB drug development.
- In vitro and in vivo nonclinical models that may help select or deselect new investigational TB drug regimens to enter into clinical development.
- Biomarkers that may help predict responses to therapy at a time earlier than standard liquid or solid culture results would allow.
- Surrogate endpoints that may be used to predict clinical benefit.
- An update on TB diagnostics.
- Options for assessing the contribution of individual drugs in a new TB treatment regimen.
- Clinical trial design challenges in pediatric and special populations.

The Agency encourages health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

III. Participating in the Public Workshop

Registration: Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by July 14, 2017, midnight eastern standard time. To register, please provide complete contact information

for each attendee, including name, title, affiliation, address, email, and telephone to TuberculosisWorkshop2017@fda.hhs.gov. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see FOR FURTHER INFORMATION CONTACT) no later than July 14, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 11, 2017. All requests to make oral presentations must be received by July 10, 2017. If selected for presentation, any presentation materials must be emailed to TuberculosisWorkshop2017@fda.hhs.gov no later than July 13, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast at the following site at <https://collaboration.fda.gov/tbdd071917>.

If you have never attended a Connect Pro event before, please 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 Web site addresses in this document, as of the date this document publishes in the Federal Register, but Web sites 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 (see ADDRESSES). A link to the transcript will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm548365.htm> approximately 45 days after the workshop.

Dated: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy,

Planning, Legislation, and Analysis.

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