4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-4170]

Establishment of a Public Docket; Clinical Trial Designs in Emerging Infectious Diseases

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to receive input on clinical trial designs in emerging infectious diseases. Interested parties are invited to submit comments, supported by research and data, regarding clinical trial designs.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2015-N-4170 for "Clinical Trial Designs in Emerging Infectious Diseases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:

FDA held a workshop on "Clinical Trial Designs in Emerging Infectious Diseases" in partnership with the National Institute of Allergy and Infectious Diseases, the HHS Office of the Assistant Secretary for Preparedness and Response, and the Centers for Disease Control and

Prevention as a step in collecting information. The objectives of the workshop were to: (1) Discuss the deployment of investigational products in the context of emerging infectious diseases, drawing on the lessons learned in the Ebola virus epidemic; (2) explore the strengths and weaknesses of different clinical trial designs for establishing the safety and efficacy of investigational products for the treatment and/or prevention of life-threatening emerging infectious diseases (EID) in resource-limited settings from scientific, ethical, and operational perspectives; (3) identify areas of consensus and areas needing further discussion, with the goal of formulating acceptable options for the deployment of investigational products in clinical trials for future EIDs; and (4) discuss planning and other factors that can impact on the ability to establish clinical trials in a timely fashion to evaluate investigational therapies. The meeting agenda, transcripts, and web cast recordings are available on the FDA Web site at http://www.fda.gov/emergencypreparedness/counterterrorism/medicalcountermeasures/aboutmcmi/ucm466153.htm. The meeting agenda and transcripts will also be available in the docket.

FDA is opening this docket to provide an avenue for the public to submit additional information that may be relevant to the design and conduct of clinical trials for establishing the safety and efficacy of investigational products for the treatment and/or prevention of life-threatening emerging infectious diseases. Individuals submitting comments are specifically invited to address the scientific, ethical, and practical considerations that should be taken into account when designing and implementing clinical trials for future emerging infectious diseases in resource-limited settings.

Dated: December 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-32724 Filed: 12/28/2015 8:45 am; Publication Date: 12/29/2015]