

making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 19, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 20, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Philip A. Bautista (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 28, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018-14795 Filed 7-10-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1835]

Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention." The purpose of this draft guidance is to assist sponsors in all phases of development of antiviral drugs for the treatment or prevention of smallpox (variola virus) infection. This draft guidance revises the draft guidance for industry entitled "Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention" issued on November 23, 2007.

DATES: Submit either electronic or written comments on the draft guidance by September 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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-2018-D-1835 for "Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention; Draft Guidance for Industry; Availability." Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6370, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.” The purpose of this draft guidance is to assist sponsors in all phases of development of antiviral drugs for the treatment or prevention of smallpox (variola virus) infection. This draft guidance addresses nonclinical development, key study design considerations for animal efficacy studies to support potential new drug application (NDA)/biologics license application (BLA) submissions under the animal rule (21 CFR part 314, subpart I, for drugs and 21 CFR part 601, subpart H, for biologics), and considerations for obtaining a human safety database.

This draft guidance revises the draft guidance for industry entitled “Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention” issued on November 23, 2007 (72 FR 65750). The revisions intend to streamline the guidance and incorporate input from a public workshop in 2009 and an advisory committee meeting in 2011. This revision contains the following changes:

- Modification and integration of several sections to focus on multidisciplinary considerations for studies in animal models of orthopoxvirus disease, including:
 - Considerations for preliminary assessments of antiviral activity in animal models
 - Key study design considerations for animal efficacy studies to support potential NDA/BLA submissions under the animal rule
 - Selection of an effective dose in humans
- Additional clarification on the following:
 - Key nonclinical virology issues related to drug development under the animal rule
 - Key pharmacology/toxicology issues
 - Considerations regarding healthy volunteer safety trials, safety data from non-smallpox clinical experience, clinical trials in the event of a public health emergency, individual patient expanded access investigational new drug applications for emergency use, and emergency use authorization
 - Key clinical pharmacology issues that may be affected by limitations in collecting clinical data
 - Key chemistry, manufacturing, and controls issues, such as the importance of developing formulations for patients who are unable to swallow solid oral dosage formulations, as well as the importance of generating stability data needed to support a long expiration dating period

- This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs for the treatment and prevention of smallpox (variola virus) infection. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 (NDAs) has been approved under OMB control number 0910–0001. The collection of information resulting from special protocol assessments has been approved under OMB control number 0910–0470. The collection of information resulting from emergency use authorization of medical products has been approved under OMB control number 0910–0595. The collection of information resulting from individual patient expanded access applications has been approved under OMB control

number 0910–0814. The collection of information resulting from good laboratory practices has been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14749 Filed 7–10–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Cancellation; Notice of Meeting

Notice is hereby given of the cancellation of the National Cancer Institute Special Emphasis Panel, August 7, 2018, 10:00 a.m. to August 7, 2018, 5:00 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, 7W260, Rockville, MD 20850 which was published in the **Federal Register** on June 8, 2018, 83 FR 26703.

This meeting has been cancelled due to no proposal submissions.

Dated: July 5, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–14757 Filed 7–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–35]

30-Day Notice of Proposed Information Collection: Production of Material or Provision of Testimony by HUD in Response to Demands in Legal Proceedings Among Private Litigants

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of