Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' The purpose of this draft guidance is to assist sponsors in all phases of development of antiviral drugs for the treatment or prevention of smallpox (variola virus) infection. This draft guidance addresses nonclinical development, key study design considerations for animal efficacy studies to support potential new drug application (NDA)/biologics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This draft guidance revises the draft guidance for industry entitled ''Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention'' issued on November 23, 2007 (72 FR 65750).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]

BILLING CODE 4164–01–P

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