Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' The purpose of this draft guidance is to assist sponsors in all phases of development of antiviral drugs for the treatment or prevention of smallpox (variola virus) infection. This draft guidance addresses nonclinical development, key study design considerations for animal efficacy studies to support potential new drug application (NDA)/biologics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This draft guidance revises the draft guidance for industry entitled ''Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention'' issued on November 23, 2007 (72 FR 65750).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

information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* August 10, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 8, 2018 at 83 FR 20850.

A. Overview of Information Collection

Title of Information Collection: Production of Material or Provision of Testimony by HUD in Response to Demands in Legal Proceedings Among Private Litigants.

OMB Approval Number: 2510–0014.

Type of Request: Revision of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: Section 15.203 of HUD's regulations in 24 CFR specify the manner in which demands for documents and testimony from the Department should be made. Providing the information specified in 24 CFR 15.203 allows the Department to more promptly identify documents and testimony which a requestor may be seeking and determine whether the Department should produce such documents and testimony.

Estimated Number of Respondents/ Estimated Number of Responses:

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
§ 15.203	106.00	1.00	106.00	1.50	159.00	$49.56	$7,880.04

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: June 25, 2018.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–14839 Filed 7–10–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–R–2018–N064; FF09R50000 18X FVRS84510900000; OMB Control Number 1018–New]

Agency Information Collection Activities; Pre-Acquisition Tracking System

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service, we) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 10, 2018.

ADDRESSES: Send your comments on the information collection request (ICR) by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–PATS in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the Service; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Service enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Service minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal