You may submit comments identified by Docket No. CDC–2018–0057 by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov* (Follow the instructions for submitting comments).
- *U.S. Mail:* Sam Tarr, Office of Safety, Security, and Asset Management (OSSAM), Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–K80, Atlanta, Georgia 30329–4027.

Instructions: All submissions must include the agency name and Docket Number. All relevant comments received will be posted to *http://www.regulations.gov* (personally identifiable information, except for first and last names, will be redacted). For access to the docket to review background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sam Tarr, Office of Safety, Security, and Asset Management (OSSAM), Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–K80, Atlanta, Georgia 30329–4027, phone: (770) 488–8170, or email: *cdc-macewv-eis@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: CDC is dedicated to protecting health and promoting quality of life through the prevention and control of disease, injury, and disability. NIOSH, one of CDC's Centers, Institutes, and Offices, was established by the Occupational Safety and Health Act of 1970. NIOSH plans, directs, and coordinates a national program to develop and establish recommended occupational safety and health standards, conduct research and training, provide technical assistance, and perform related activities to ensure safe and healthful working conditions for every working person in the United States.

In 1997, NIOSH assumed the lease for a facility referred to as the Lake Lynn Experimental Mine (LLEM) when the mine safety and health function was transferred from the Bureau of Mines (BOM) to NIOSH. The LLEM facility had been leased by BOM since 1982. The LLEM was located 60 miles south of Pittsburgh, Pennsylvania. The LLEM and above ground fire testing facility was primarily used for studies and research on mine explosions, mine seals, mine rescue, ventilation, diesel exhaust, new health and safety technologies, ground control, and fire suppression. After December 2012, the property was no longer available for long-term leasing. CDC attempted to purchase the LLEM underlying property, but LLEM was vacated by the Government after market-based purchase offers were rejected by the property owners.

In 2013, CDC completed a Project Development Study to outline a design solution for the replacement of the LLEM. The study presented the facility and site requirements and design concepts for the replacement facilities. In 2016, to identify potentially available locations that could accommodate the space requirements defined in the 2013 study, GSA issued (on behalf of CDC) two separate Request for Expressions of Interest (REOI) for a site, developed or undeveloped, that could be used for the new underground safety research facility. The first REOI, advertised in June 2016, contained a limited delineated area within a 200-mile radius of the LLEM. The REOI set forth criteria that would be used to evaluate the suitability of the submitted sites. One expression of interest that had the potential to meet the minimum criteria was received. After further evaluation, however, the site was found to be non-viable.

The second REOI was issued in October 2016 and expanded the delineated area to the contiguous United States. Three expressions of interest were received. One did not meet the minimum criteria, and a second expression of interest did not contain all necessary information to evaluate the offer. The offeror of the second site did not respond to subsequent GSA inquiries.

The third potential site met the minimum criteria and was determined to be a viable site. The site is located near Mace, West Virginia, and straddles the Randolph and Pocahontas County lines.

In accordance with NEPA, as implemented by the CEQ regulations (40 CFR parts 1500–1508), CDC is initiating the preparation of an EIS for the proposed acquisition of the site and construction of a new underground safety research facility on the Site. Under NEPA, Federal agencies are required to evaluate the environmental effects of their proposed actions and a range of reasonable alternatives to the proposed action before making a decision. At a minimum, the EIS will evaluate the following two alternatives: The Proposed Action Alternative (acquisition of the Site and construction of a new underground safety research facility) and the No Action Alternative.

Scoping Process: In accordance with NEPA, a public scoping process will be conducted to establish the range of issues to be addressed during the preparation of the EIS. Scoping is an early and open process for determining the scope of issues to be addressed and identifying issues that should be taken into account in selecting an alternative for implementation. To that end, during the scoping process, CDC will actively seek input from interested people; organizations; federally recognized Native American tribes; and federal, state, and regional agencies.

The purpose of this Notice is to inform interested parties regarding CDC's plan to prepare an EIS for the proposed Site acquisition in Mace, West Virginia, and the development of the Site into an underground safety research facility; to provide information on the nature of the Proposed Action; and to initiate the scoping process. The public scoping meeting will be held on June 26, 2018, at the Linwood Community Library, 72 Snowshoe Drive, Slatyfork, West Virginia 26291, from 5:30 p.m. to 8:30 p.m. Eastern Time. The public scoping meeting will be in open house format. General information on the Site and the Proposed Action will be provided, and representatives of CDC and GSA will be available to answer one-on-one questions. There will be no formal presentation or question-and-answer session. Participants may arrive at any time between 5:30 p.m. and 8:30 p.m. Eastern Time. Comment forms will be provided for written comments, and a stenographer will be available to transcribe oral comments. Through the NEPA scoping process, CDC will also facilitate consultation with the public as required by Section 106 of the NHPA.

Dated: June 7, 2018.

Sandra Cashman,

Executive Secretary Centers for Disease Control and Prevention.

[FR Doc. 2018–12660 Filed 6–13–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1918]

Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis; 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 ''Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for

Pre-Exposure Prophylaxis.'' This draft guidance provides nonclinical and clinical recommendations specific to the development of systemic drug products, with a focus on long-acting systemic drug products, regulated within the Center for Drug Evaluation and Research (CDER) at FDA for the prevention of sexually acquired human immunodeficiency virus-1 (HIV–1) infection.

DATES: Submit either electronic or written comments on the draft guidance by August 13, 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–1918 for ''Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis.'' 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: Kimberly Struble, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6374, Silver Spring, MD 20993–0002, 301–794–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis.'' This draft guidance provides nonclinical and clinical recommendations specific to the development of systemic drug products, with a focus on long-acting systemic drug products, regulated within CDER at FDA for the prevention of sexually acquired HIV–1 infection.

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 systemic drug products for pre-exposure prophylaxis of HIV–1 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 draft 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

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: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12761 Filed 6–13–18; 8:45 am]

BILLING CODE 4164–01–P