agencies, entities, and persons is reasonably necessary to assist in connection with HHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

b. Information may be disclosed to another federal agency or federal entity when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records are stored electronically.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the parent's, guardian's, or third-party caretaker's name or SSN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Upon approval of a disposition schedule by the National Archives and Records Administration (NARA), the records will be deleted when eligible for destruction under the schedule, if the records are no longer needed for administrative, audit, legal, or operational purposes. ACF anticipates requesting NARA's approval of retention periods of approximately 60 days for the information contained in the transmission files (*i.e.,* long enough to confirm receipt or to resend if necessary) and up to 7 years for the audit log records. Approved disposal methods for electronic records and media include overwriting, degaussing, erasing, disintegration, pulverization, burning, melting, incineration, shredding, or sanding.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The system leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRAMP) requirements. Specific administrative, technical, and physical controls are in place to ensure that the records collected, maintained, and transmitted using the OCSE Data Center General Support System are secure from unauthorized access. Access to the records within the system is restricted to authorized personnel who are advised of the confidentiality of the records and the civil and criminal penalties for misuse, and who sign a nondisclosure oath to that effect. Agency personnel are provided privacy and security training before being granted access to the records and annually thereafter. Additional safeguards include protecting the facilities where records are stored or accessed with security guards, badges, and cameras; limiting access to electronic databases to authorized users based on roles and either two-factor authentication or user ID and password (as appropriate); using a secured operating system protected by encryption, firewalls, and intrusion detection systems; reviewing security controls on a periodic basis; and using secure destruction methods prescribed in NIST SP 800–88 to dispose of eligible records. All safeguards conform to the HHS Information Security and Privacy Program, *https://www.hhs.gov/ocio/securityprivacy/index.html.*

RECORD ACCESS PROCEDURES:

To request access to a record about you in this system of records, submit a written access request to the System Manager identified in the ''System Manager'' section of this System of Records Notice (SORN). The request must reasonably describe the record sought and must include (for contact purposes and identity verification purposes) your full name, current address, telephone number and/or email address, date and place of birth, and signature, and (if needed by the agency) sufficient particulars contained in the records (such as your SSN) to enable the System Manager to distinguish between records on subject individuals with the same name. In addition, to verify your identity, your signature must be notarized or the request must include your written certification that you are the individual who you claim to be and that you understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. You may request that copies of the records be sent to you, or you may request an appointment to review the records in person (including with a person of your choosing, if you provide written authorization for agency personnel to discuss the records in that person's presence). You may also request an accounting of disclosures that have been made of records about you, if any.

CONTESTING RECORD PROCEDURES:

To request correction of a record about you in this system of records, submit a written amendment request to the System Manager identified in the ''System Manager'' section of this SORN. The request must contain the same information required for an access request and include verification of your identity in the same manner required for an access request. In addition, the request must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

To find out if the system of records contains a record about you, submit a written notification request to the System Manager identified in the ''System Manager'' section of this SORN. The request must identify this system of records, contain the same information required for an access request, and include verification of your identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2021–27324 Filed 12–20–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0548]

Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Draft Guidance for Industry'' that appeared in the **Federal Register** on October 22, 2021. The Agency is taking this action in response

to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Draft Guidance for Industry'' published October 22, 2021 (86 FR 58672). Submit either electronic or written comments by February 4, 2022 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–2021–D–0548 for ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Draft Guidance for Industry.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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

Submit written requests for single copies of this 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: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2500, *dianne.paraoan@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *stephen.ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 22, 2021, FDA published a notice of availability with a 60-day comment period to provide comments on the draft guidance entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data: Draft Guidance for Industry.'' FDA has received requests to extend the comment period to allow sufficient time to develop and submit meaningful comments. FDA has considered the requests and is extending the comment period for 45 days, until February 4, 2022. The Agency believes that a 45-day extension allows adequate time for interested persons to submit comments.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27521 Filed 12–20–21; 8:45 am]

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