FOR FURTHER INFORMATION CONTACT: Ben Firschein, Office of Inspections and Investigations, Division of Inspectorate Policy, Food and Drug Administration, 12420 Parklawn Drive, Element Building, Rockville MD 20857, *Ben.Firschein@fda.hhs.gov,* 240–402–0613; or Patrick Clouser, Office of Inspections and Investigations, Division of Inspectorate Policy, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, *Patrick.Clouser@fda.hhs.gov,* 240–402–5276.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Conducting Remote Regulatory Assessments—Questions and Answers.'' The final guidance makes further revisions to and replaces the revised draft guidance entitled ''Conducting Remote Regulatory Assessments—Questions and Answers; Draft Guidance for Industry,'' which was announced in the **Federal Register** on January 26, 2024 (89 FR 5244) (hereafter, the ''revised draft guidance''). FDA issued the revised draft guidance to describe the Agency's thinking regarding its use of RRAs, to help increase the industry's understanding of voluntary and mandatory RRAs, and to facilitate FDA's process for conducting remote assessments for FDA-regulated products outside of the COVID–19 public health emergency. The revised draft guidance reflected consideration of comments on a preceding draft guidance of the same title as well as revisions to align with 2022 changes in law,[1] including to address a requirement to issue guidance [2] related to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (*i.e.,* requests for records in advance of or in lieu of an inspection; such requests are a type of RRA). The comment period for the revised draft guidance ended on March 26, 2024.

The final guidance additionally reflects consideration of comments from interested parties on the revised draft guidance. Specifically, the final guidance includes changes to: (1) distinguish more clearly between mandatory and voluntary RRA requests; (2) clarify how FDA intends to inform establishments of the terms of participation in voluntary RRAs and obtain their consent to conduct the RRA; (3) facilitate transparency and consistency in FDA's use of RRAs across regulated products, as applicable; (4) clarify mechanisms for electronic records reviews and conditions under which live data access might occur; and (5) address concerns about confidentiality and security of establishment information reviewed by FDA. The final guidance also addresses the 2022 requirement for issuance of final guidance [3] relating to the Agency's use of section 704(a)(4) of the FD&C Act.

The final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The final guidance represents the current thinking of FDA on ''Conducting Remote Regulatory Assessments.'' 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

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

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11754 Filed 6–25–25; 8:45 am]

BILLING CODE 4164–01–P

[1] See sections 3611, 3612, and 3613 of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023, Public Law 117–328 (2022). Among changes made by FDORA were adding (in addition to drug establishments) device establishments, and sites, entities, or facilities subject to bioresearch monitoring (BIMO) inspections, to mandatory records request authority under section 704(a)(4) of the FD&C Act.

[2] FDORA section 3611(b)(2) required FDA to issue (or update) guidance as draft, and then, issue final guidance, describing the circumstances under which the Agency intends to use its authority to issue requests for records or other information under section 704(a)(4) of the FD&C Act (as amended by FDORA), the processes for firms to respond, and the factors for determining whether a facility has appropriately and timely responded.

[3] Id.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2315]

Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment; 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 final guidance for industry entitled ''Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of early Lyme disease as manifested by erythema migrans (EM). This guidance finalizes the draft guidance of the same name issued on February 1, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on June 26, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2022–D–2315 for ''Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.'' 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Shabnam Naseer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6239, Silver Spring, MD 20993, 301–796–8539.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.''

The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of early Lyme disease as manifested by EM.

This guidance finalizes the draft guidance of the same name issued on February 1, 2023 (88 FR 6759). FDA made clarifying edits in response to pertinent public comments that were received on the background section, as well as regarding endpoints (*e.g.,* patient-reported outcome development), missing data, and safety database size.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 pertaining to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 201 pertaining to prescription product labeling requirements have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *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: June 20, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11809 Filed 6–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Authorization of Emergency Use of In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Cepheid for the Xpert Xpress SARS–CoV–2 test. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reason for revocation, is reprinted at the end of this document.