syrup, 2 mg/5 ml), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 mg/5 ml), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 mg/5 ml), was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 mg/5 ml), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DEXCHLORPHENIRAMINE MALEATE (dexchlorpheniramine maleate, oral syrup, 2 mg/5 ml), in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23419 Filed 12–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5021]

Processes and Practices Applicable to Bioresearch Monitoring Inspections; 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 ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' This final guidance is being issued to comply with the Food and Drug Omnibus Reform Act of 2022, which directs the Agency to issue guidance describing the processes and practices applicable to inspections of sites and facilities inspected under FDA's Bioresearch Monitoring inspection program, to the extent not specified in existing publicly available FDA guides and manuals. The guidance covers the following: the types of records and information required to be provided, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.

DATES: The announcement of this guidance is published in the **Federal Register** on December 18, 2025.

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–2023–D–5021 for ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' 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 the guidance to the Division of Inspectorate Policy, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by emailing the Office of Inspections and Investigations at *OIIPolicyStaffs@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Darby Hull, Office of Inspections and Investigations, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, *Darby.Hull@fda.hhs.gov,* 301–796–5949.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' This finalizes the draft guidance entitled ''Processes and Practices Applicable to Bioresearch Monitoring Inspections; Guidance for Industry,'' which was announced in the **Federal Register** on June 5, 2024 (89 FR 48170) (hereafter, the ''draft guidance'').

FDA is issuing this final guidance to comply with section 3612(b)(2) of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023.

This provision of FDORA directs FDA to issue guidance describing the processes and practices applicable to inspections of certain sites and facilities, to the extent not specified in existing publicly available FDA guides and manuals for such inspections. These sites and facilities are inspected under FDA's Bioresearch Monitoring (BIMO) inspection program. Specifically, this guidance addresses the following (to the extent not publicly available in FDA guides and manuals): the types of records and information required to be provided, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.

FDA's BIMO program is a comprehensive portfolio of programs designed to assess and monitor all aspects of the conduct and reporting of FDA-regulated research as well as certain postmarketing activities through on-site inspections, investigations, and Remote Regulatory Assessments. The BIMO program was established to assess the quality and integrity of data submitted to the Agency in support of regulatory decision-making, as well as to provide for protection of the rights, safety, and welfare of human and animal trial participants involved in FDA-regulated research. The program assesses compliance with statutory requirements and FDA's regulations governing the conduct of nonclinical and clinical studies, and applicable postmarketing activities.

FDA also is confirming that the following two guidances will be withdrawn upon publication of this guidance, as their substance is superseded by this final guidance and other guidances and related documents described in this final guidance: the 2010 ''Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators,'' and the 2006 ''Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Institutional Review Board Inspections.''

FDA received 15 comments on the draft guidance. The comments primarily came from industry (including trade and professional associations). The comment period for the draft guidance ended on August 5, 2024. Commenters expressed interest in the Agency's current practices with respect to accessing electronic databases during an inspection, the logistics of the Agency's inspection pre-announcement notices and communications, and types of communication after an inspection.

This final guidance reflects consideration of the public comments on the draft guidance. Specifically, the final guidance, among other things, contains changes to: (1) clarify the Agency's practices for accessing and obtaining copies of electronic records; (2) provide additional details with respect to the Agency's inspection pre-announcement notices and communications; and (3) offer additional information on post-inspection communications.

This 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 ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' 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

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* or *https://www.regulations.gov.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23404 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4682]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph), approved September 19, 2025, meets the