++ QUAD A's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–23930 Filed 10–16–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4774]

Temporary Policies for Compounding Certain Parenteral Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Temporary Policies for Compounding Certain Parenteral Drug Products.'' As of October 10, 2024, pursuant to the Public Health Service Act (PHS Act), Department of Health and Human Services (HHS) Secretary Becerra has determined that public health emergencies (PHEs) exist as a result of the consequences of Hurricane Helene in the States of North Carolina, Florida, Georgia, Tennessee, and South Carolina, and as a result of the consequences of Hurricane Milton in the State of Florida. In late September 2024, Hurricane Helene had a devastating impact on one of the largest manufacturers of certain intravenous and peritoneal dialysis solutions in the United States. This guidance describes the FDA's regulatory and enforcement priorities regarding the compounding of certain parenteral drug products by outsourcing facilities and by State-licensed pharmacies and Federal facilities that are not registered with FDA as outsourcing facilities.

DATES: The announcement of the guidance is published in the **Federal Register** on October 17, 2024.

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–2024–D–4774 for ''Temporary Policies for Compounding Certain Parenteral Drug Products.'' 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 Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Gabrielle Cosel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

As of October 10, 2024, pursuant to section 319(a) of the Public Health Service Act (42 U.S.C. 247d) (PHS Act), HHS Secretary Becerra has determined that public health emergencies (PHEs) exist as a result of the consequences of Hurricane Helene in the States of North Carolina, Florida, Georgia, Tennessee, and South Carolina, and as a result of the consequences of Hurricane Milton in the State of Florida. FDA is aware of reports from hospitals, health systems, and State-licensed pharmacies that they have experienced difficulties obtaining certain intravenous solutions. FDA is closely monitoring this situation and using all of its applicable authorities to work with the manufacturers of intravenous solutions to increase supply. For example, FDA has facilitated the temporary importation of intravenous solution products from certain foreign facilities, detailed at: *https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina.*

However, we recognize that hospitals, health systems, State-licensed pharmacies, and applicable Federal facilities have concerns about assuring access to intravenous solutions as the impacts of the hurricanes continue. Therefore, FDA is issuing this policy to describe the FDA's regulatory and enforcement priorities regarding the compounding of certain parenteral drug products for hospitals by outsourcing facilities and by State-licensed pharmacies and Federal facilities that are not registered with FDA as outsourcing facilities.

We are announcing the availability of a guidance for industry entitled ''Temporary Policies for Compounding Certain Parenteral Drug Products.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). This guidance document is being implemented immediately to help ensure patient access to certain parenteral drug products, such as intravenous fluids, which are essential in the care of patients, including those who are critically ill and those undergoing surgery. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

The guidance represents the current thinking of FDA on ''Temporary Policies for Compounding Certain Large Volume Parenteral Drug Products for Hospitals.'' 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 for current good manufacturing practice requirements have been approved under OMB control number 0910–0139. The collections of information for registration of human drug compounding outsourcing facilities under section 503B of the FD&C Act and associated fees under section 744K of the FD&C Act (21 U.S.C. 379j–62) have been approved under OMB control number 0910–0776. The collections of information for human drug compounding and adverse event reporting under sections 503A and 503B (21 U.S.C. 353a and 353b) of the FD&C Act have been approved under OMB control number 0910–0800. The collections of information for adverse event and product experience reporting under the MedWatch System has been approved under OMB control number 0910–0291.

To the extent this guidance also contains a new collection of information not approved under a current collection, a PHE waiver from the PRA has been granted by HHS on October 11, 2024, under section 319(f) of the Public Health Service Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 11, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–23954 Filed 10–16–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5868]

Requests for Reconsideration at the Division Level Under the Generic Drug User Fee Amendments; 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 ''Requests for Reconsideration at the Division Level Under GDUFA.'' This guidance provides recommendations on the procedures for applicants of abbreviated new drug applications (ANDAs) that wish to pursue a request for reconsideration within the review discipline at the division level or original signatory authority. This guidance reflects the most recent reauthorization of the Generic Drug User Fee Amendments (GDUFA III) and clarifies what matters are appropriate for requests for reconsideration. This guidance finalizes the draft guidance for industry of the same title issued on January 11, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on October 17, 2024.

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: