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]

BILLING CODE 4164–01–P

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:

• *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–2017–D–5868 for ''Requests for Reconsideration at the Division Level Under GDUFA.'' 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: David Coppersmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20903, 301–796–9193, *David.Coppersmith@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Requests for Reconsideration at the Division Level Under GDUFA.'' This guidance provides recommendations on the procedures for applicants of ANDAs that wish to pursue a request for reconsideration within the review discipline at the division level or original signatory authority. Requests within the scope of this guidance document should concern certain actions that relate to an ANDA and have scientific significance.

During the assessment of an ANDA, FDA considers important issues that are central to product evaluation. Sometimes, an applicant may disagree with FDA, and because these disagreements often involve intricate matters, it is critical to have procedures in place to ensure open and prompt consideration of an applicant's concern(s). The procedures and policies described in this guidance are intended to formalize FDA's current and historical practices and to continue to promote rapid and fair resolution of eligible requests between an applicant and FDA.

This guidance finalizes the draft guidance for industry of the same title issued on January 11, 2024 (89 FR 1923). FDA received no comments on the draft guidance. No changes were made other than editorial changes.

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 ''Requests for Reconsideration at the Division Level Under GDUFA.'' 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 314 have been approved under OMB control number 0910–0001. The collections of information pertaining to the GDUFA III commitment letter, meetings related to generic drug development, and the Generic Drug User Fee Program have been approved under OMB control number 0910–0727.

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: October 9, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–23967 Filed 10–16–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Generic Information Collection Request for Health Resources and Services Administration Stakeholder Gatherings

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 18, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Umbrella Generic Information Collection Request for Information Collections Related to HRSA Gatherings, OMB No. 0906–xxxx—New.

Abstract: HRSA conducts gatherings for various purposes, including conferences, meetings, workshops, webinars, trainings, communities of practice, focus groups, and other in-person or virtual gatherings for individuals and organizations that are interested in HRSA programs. To ensure that HRSA has sufficient information to plan, convene, administer, and evaluate the effectiveness of these gatherings, HRSA must collect information from potential attendees, such as contact information, organizational information, logistical information (*e.g.,* preferred delivery methods), accommodation needs, and feedback about the gathering's content. Furthermore, HRSA may conduct a test of knowledge to see what attendees know about the subject matter before or during the meeting or focus group. After the gathering concludes, attendees may be asked to complete an evaluation form and/or a test of knowledge to measure the gathering's effectiveness. In some instances, attendees may also apply and/or submit an abstract for prescreening to be selected for attendance.

An illustrative, but not exhaustive, list of examples of standardized information collection activities related to HRSA gatherings include:

- *Registration Forms:* Information collected includes name, contact information, organization/affiliation, demographic information (age, race or ethnicity, occupation, and location), and attendee accommodation needs.
- *Application Forms for panels, posters, or other presentation formats:* For application forms, information collected also includes title, author(s), organization/affiliation, and presentation abstract, in addition to the information contained in the registration form.
- *Focus Groups:* Information collected includes attendee/presenter responses to standard questions regarding topics posed to smaller groups during HRSA gatherings.
- *Pre-/Post-gathering Forms:* Information collected includes attendee/presenter preferences, feedback, pre-/post-meeting questions, and tests of knowledge in response to standard questions.

A 60-day notice published in the **Federal Register** on June 21, 2024, 89 FR 52067–68. HRSA received one comment that was outside the scope of the proposed information collection.

Need and Proposed Use of the Information: The purpose of collections under this umbrella generic information collection is to gather appropriate information to plan, administer, and evaluate HRSA gatherings. While HRSA can evaluate the general need for and the overall practical utility of such information collection in advance, HRSA may not be able to determine the details of the specific individual collections until a later time. The planning for these gatherings is often on a quick timeline and the standard timeline to comply with a full request under the Paperwork Reduction Act could inhibit HRSA's ability to collect information to inform these activities. The information collected is expected to be voluntary, low-burden, and uncontroversial. Therefore, an umbrella generic is requested to allow for quick turnaround requests for similar information collections related to these activities.

As this Generic ICR for HRSA Stakeholder Gatherings will focus on the awareness, understanding, attitudes, preferences, or experiences of HRSA customers or other stakeholders (*e.g.,* funding recipients and their delivery partners, potential funding applicants) relating to existing or future services, products, or communication materials, the Fast Track Process should apply to this information collection. Therefore, HRSA requests OMB provide a response on individual generic information collections within 5 business days.

Likely Respondents: Attendees and presenters at HRSA conferences, meetings, workshops, webinars, trainings, communities of practice, and other in-person, virtual, or hybrid gatherings. Attendees and presenters may include HRSA funding recipients, individuals seeking to participate in a HRSA-funded program, members of the public who utilize HRSA-funded resources, contractors, researchers, and other members of the public. Responses to any information collections under this Generic ICR for HRSA Stakeholder Gatherings are not required to obtain or retain any benefit.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below. HRSA conducted this estimate based on reviewing burden estimates of forms