metered (''Draft Guidance on Fluticasone Propionate'').

In May 2021, Optinose US, Inc. (OptiNose) submitted a citizen petition requesting, among other things, that FDA not approve an ANDA referencing XHANCE (fluticasone propionate) nasal spray, metered, unless the applicant demonstrates bioequivalence and therapeutic equivalence through certain studies, and that FDA issue a product-specific guidance for fluticasone propionate nasal spray, metered, that recommends studies consistent with those requested in the petition. (Docket No. FDA–2021–P–0530, available at *https://www.regulations.gov*). FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidance entitled ''Draft Guidance on Fluticasone Propionate'' before responding to the petition. FDA's issuance of the draft guidance on generic fluticasone propionate nasal spray, metered does not represent a final decision on the issues raised in the petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Draft Guidance on Fluticasone Propionate.'' 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. As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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: May 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09067 Filed 5–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0874]

Revocation of Emergency Use of a Drug Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Fresenius Medical Care North America (Fresenius) for multiFiltrate PRO System and multiBic/multiPlus solutions (EUA 048), and to Baxter Healthcare Corp. (Baxter) for REGIOCIT (EUA 068). FDA revoked the Authorizations on January 16, 2025, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, including an explanation of the reasons for the revocations, are reprinted in this document.

DATES: These Authorizations are revoked as of January 16, 2025.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Commander Andrea Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 2nd Floor, Silver Spring, MD 20993–0002, 301–796–2210 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On April 30, 2020, FDA issued an Authorization to Fresenius, for multiFiltrate PRO System and multiBic/multiPlus solutions, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on September 11, 2020 (85 FR 56231), as required by section 564(h)(1) of the FD&C Act.

On August 13, 2020, FDA issued an Authorization to Baxter, for REGIOCIT, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on February 19, 2021 (86 FR 10290), as required by section 564(h)(1) of the FD&C Act.

The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on January 14, 2025, Fresenius requested revocation of, and on January 16, 2025, FDA revoked, the Authorization for multiFiltrate PRO System and multiBic/multiPlus solutions. Because Fresenius has informed FDA that it does not intend to offer the multiFiltrate Pro System and multiBic/multiPlus solutions under the EUA in the United States anymore, Fresenius requested FDA revoke the EUA for multiFiltrate PRO System and multiBic/multiPlus solutions. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on January 14, 2025, Baxter requested revocation of, and on January 16, 2025, FDA revoked, the Authorization for REGIOCIT. Because Baxter has informed FDA that it does not intend to offer this product under the EUA in the United States anymore, Baxter requested FDA

revoke the EUA for REGIOCIT. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for multiFiltrate PROSystem and multiBic/multiPlus solutions and revoked the EUA for REGIOCIT. These revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.regulations.gov/.*

BILLING CODE 4164–01–P

January 16, 2025

Fresenius Medical Care North America
Attention: Renee Howard, M.S.
Vice President Global Drug – Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: Revocation of EUA 048

Dear Ms. Howard:

This letter is in response to the request from Fresenius Medical Care North America (Fresenius) that the U.S. Food and Drug Administration (FDA) revoke the EUA for the multiFiltrate PRO System and multiBic/multiPlus solutions. This EUA was issued initially on April 30, 2020.

Fresenius has informed the FDA that it does not intend to offer the multiFiltrate PRO System and multiBic/multiPlus solutions under the EUA in the United States anymore. The multiFiltrate PRO System and the multiBic solution have obtained marketing clearance for certain uses under section 510(k) of the Federal Food, Drug and Cosmetic Act (the Act).[1] FDA understands that Fresenius will issue a communication to notify healthcare facilities and providers that have received the multiFiltrate PRO System and multiBic/multiPlus solutions under the EUA of this revocation and to stop using the multiBic solution as a replacement solution in continuous renal replacement therapy. The use of the multiBic solution as a replacement solution in continuous renal replacement therapy is no longer authorized under the EUA and such use has not obtained FDA-approval. However, and consistent with FDA policy[2], FDA does not intend to object to the use of the multiBic solution remaining in distribution when used consistent with the labeling conditions detailed under K233159 until such product has expired.

The authorization of a drug or device for emergency use under section 564 of the Act (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). For the reasons stated in Fresenius' request, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 048 for the multiFiltrate PRO System and multiBic/multiPlus solutions pursuant to section 564(g)(2)(C) of the Act. As of the date of this

[1] The multiFiltrate PRO System obtained 510(k) clearance under K220281. The multiBic solution, marketed as pureFlow Dialysate Solutions, obtained 510(k) clearance under K233159. The multiBic solution has not obtained FDA-approval under section 505 of the Act for use as a replacement solution in continuous renal replacement therapy.

[2] See FDA's guidance titled *Transition Plan for Medical Devices Issued Emergency Use Authorizations Related to COVID-19* (March 2023).

January 16, 2025

Baxter Healthcare Corporation
Attention: Ximena Semensato
Senior Manager, Global Regulatory Affairs
Acute Therapies
1 Baxter Parkway
DF64E-087
Deerfield, IL 60015

Re: Revocation of EUA 068

Dear Ms. Semensato:

This letter is in response to the request from Baxter Healthcare Corporation (Baxter) that the U.S. Food and Drug Administration (FDA) revoke the EUA for REGIOCIT. This EUA was issued initially on August 13, 2020. Baxter has informed the FDA that it does not intend to offer REGIOCIT under the EUA in the United States anymore. FDA understands that Baxter will issue a communication to notify healthcare facilities and providers that have received REGIOCIT under the EUA of this revocation and to stop using REGIOCIT with instructions for product return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Act (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with REGIOCIT, the Agency recognizes that FDA-approved replacement solutions are in sufficient supply to meet the public health need. Accordingly, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

FDA hereby revokes EUA 068 for REGIOCIT pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, REGIOCIT is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Dated: May 7, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09065 Filed 5–20–25; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0279]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 21, 2025.

ADDRESSES: Submit your comments to Natalie Klein, *Natalie.Klein@hhs.gov* and *PRA@hhs.gov* or by calling (240) 453–6900.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier ''0990–0279–60D'' and project title, ''Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form'' for reference, to Natalie Klein, email: *Natalie.Klein@hhs.gov, PRA@hhs.gov* or by calling (240) 453–6900.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form.

Type of Collection: Revision.

OMB No.: 0990–0279.

Abstract: The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a revision of the currently approved collection for the Office of Management and Budget (OMB) No. 0990–0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form. The revision request involves implementing a burden reducing change. Specifically, OHRP is seeking to