Dated: May 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance on Fluticasone Propionate; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a new draft guidance for industry entitled ''Draft Guidance on Fluticasone Propionate.'' The new draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for fluticasone propionate nasal spray, metered.

DATES: Submit either electronic or written comments on the draft guidance by July 21, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–2007–D–0369 for ''Draft Guidance on Fluticasone Propionate.'' 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993–0002, 240–402–1062, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. This notice announces the availability of a new draft product-specific guidance on generic fluticasone propionate nasal spray, metered.

FDA initially approved new drug application (NDA) 209022 XHANCE (fluticasone propionate) nasal spray, metered, in September 2017. We are now issuing a draft guidance for industry on, among other things, BE recommendations for generic fluticasone propionate nasal spray,

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.

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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