• 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–2025–D–1757 for ''Oncology Therapeutic Radiopharmaceuticals: Dosage Optimization During Clinical Development.'' 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:** Oncology Center of Excellence, Food and Drug Administration, *OCE-Guidances@fda.hhs.gov;* or William Maguire, Center for Drug Evaluation and Research, Food and Drug Administration, 240–402–7225.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Dosage Optimization During Clinical Development.'' This guidance is intended to assist sponsors in identifying an optimized dosage for RPT for oncology indications during clinical development and prior to submitting a marketing application for a new indication and usage. Dosages of RPT have typically been limited to normal organ absorbed dose limits derived from external beam radiotherapy (EBRT) data. However, differences in physical properties and treatment delivery between RPT and EBRT lessen the applicability of these organ absorbed dose limits to RPT. In addition, RPT have the potential to cause delayed, cumulative, and/or irreversible toxicity that is not captured in traditional dose-finding trials. This guidance provides considerations for RPT dosage optimization in RPT development programs, including safeguards to mitigate the risk of unacceptable long-term toxicity from RPT dosages that exceed EBRT limits or previously characterized RPT dosages. The recommendations should be considered along with the FDA guidance entitled ''Optimizing the Dosage of Human Prescription Drugs and Biological Products for the treatment of Oncologic Diseases'' (August 2024).

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 ''Oncology Therapeutic Radiopharmaceuticals: Dosage Optimization During Clinical Development.'' 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 final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

## 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 in 21 CFR part 312 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 314 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: August 14, 2025.

**Grace R. Graham,**

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

[FR Doc. 2025–15797 Filed 8–18–25; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–2396]**

### Lessons Learned From the Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual-only public workshop entitled ''Lessons Learned

From the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Program.'' This workshop fulfills a commitment in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII) to hold a public meeting to discuss best practices and lessons learned from this pilot program. Convened by the Duke-Robert J. Margolis, MD Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement between FDA and Duke-Margolis, the workshop will feature sponsors and FDA experience under this pilot program and will solicit input on future directions for FDA policy and programs to facilitate expedited CMC development of products under an investigational new drug application (IND), where indicated based upon the anticipated clinical benefits.

**DATES:** The public workshop will be held virtually on September 10, 2025, from 1:00 p.m. to 5:00 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by October 15, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Standard Time (EST) on October 15, 2025.

Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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–2022–N–2396 for ''Lessons Learned from the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) program; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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. EST, 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.

**FOR FURTHER INFORMATION CONTACT:** Tanya Clayton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0871.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Development programs for the Center for Biologics Evaluation and Research (CBER)- and the Center for Drug Evaluation and Research (CDER)-regulated drugs and biologics intended to diagnose, treat, or prevent a serious disease or condition where there is an unmet medical need may have accelerated clinical development timelines. Yet, marketing applications for products in expedited development programs still need to meet FDA's approval standards, including manufacturing facility compliance with current good manufacturing practice (CGMP). Products with accelerated clinical development activities may face challenges in expediting CMC development activities to align with the accelerated clinical timelines.

As described in the PDUFA VII Commitment Letter for fiscal years (FYs) 2023 Through 2027, FDA implemented the CDRP program to facilitate CMC readiness for selected CBER- and CDER-regulated products with accelerated clinical development timelines. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, such as those described in the FDA guidance for industry entitled ''Expedited Programs

for Serious Conditions—Drugs and Biologics'' (May 2014), as applicable. Under this CDRP program, participating sponsors are able to discuss their product development strategies and goals with FDA review staff during two dedicated Type B meetings, as well as additional CMC-focused discussions.

This public workshop fulfills FDA's commitment under the PDUFA VII letter (available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027;* see section N.4.c.) to hold a public meeting focused on CMC aspects of expedited development including case studies, lessons learned, and stakeholder input regarding the CDRP, and to solicit industry and public feedback.

## II. Topics for Discussion at the Public Workshop

This public workshop is intended as an information gathering step in support of the strategy paper FDA will subsequently develop. That strategy paper will outline FDA's planned policy and programmatic response to support expediting CMC readiness when the clinical benefit of an investigational-stage product warrants it. The public workshop will feature discussions on CMC aspects of expedited development, including case studies, illustrating best practices and lessons learned from the CDRP. The workshop will also provide a forum for industry and the public to make recommendations on expediting CMC development.

Workshop updates, agenda, and background materials, if any, will be made available prior to the workshop at the CDRP web page *https://www.fda.gov/drugs/pharmaceutical-quality-resources/chemistry-manufacturing-and-controls-development-and-readiness-pilot-cdrp-program.*

## III. Participating in the Public Workshop

*Registration:* To register for the public workshop, please visit the following website: *https://healthpolicy.duke.edu/events/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-0.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration will end at 11:59 p.m. Eastern Time on September 9, 2025. Registration is free, and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register. If you need special accommodations due to a disability, please contact *Margolisevents@duke.edu* no later than 5:00 p.m. Eastern Time on August 27, 2025. Please note, closed captioning will be available automatically.

*Transcript:* Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: August 14, 2025.

**Grace R. Graham,**

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

[FR Doc. 2025–15799 Filed 8–18–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–P–5470]**

## Determination That RIFADIN (Rifampin) Capsules, 150 Milligrams and 300 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that RIFADIN (rifampin) capsules, 150 milligrams (mg) and 300 mg, were not withdrawn from sale for reasons of safety or effectiveness to the extent that the drugs can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements, including satisfying any applicable acceptable intake limit for nitrosamine impurities.

**FOR FURTHER INFORMATION CONTACT:** Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 240–893–4962, *robin.fastenau@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but it must be made prior to approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

RIFADIN (rifampin) capsules, 150 mg and 300 mg, are the subject of NDA 050420, held by Sanofi Aventis US LLC, and initially approved on May 21, 1971. RIFADIN (rifampin) capsules, 150 mg and 300 mg, are indicated for the treatment of all forms of tuberculosis and for the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx.

RIFADIN (rifampin) capsules, 150 mg and 300 mg, have not been marketed in the United States since their voluntary discontinuation from sale in November 2020.

Novitium Pharma LLC submitted a citizen petition dated November 21, 2024 (Docket No. FDA–2024–P–5470), under 21 CFR 10.30, requesting that the Agency determine whether RIFADIN (rifampin) capsules, 150 mg and 300 mg, were withdrawn from sale for reasons of safety or effectiveness.

FDA has identified a number of active pharmaceutical ingredients (APIs) that