judgment against him for the offenses of one felony count of Conspiracy to Import Schedule II and Schedule IV Controlled Substances in violation of 21 U.S.C. 963 and one felony count of Money Laundering Conspiracy in violation of 18 U.S.C. 1956(h). The underlying facts supporting the conviction are as follows: As contained in the Information and Plea Agreement from his case, Mr. Kalita along with others devised a drug scheme where he and his co-conspirators would process drug transactions for India based pharmacies who marketed their illegal drugs through the internet. By at least March of 2020, Mr. Kalita expanded his drug scheme to include actual shipment of drugs from India to customers in the United States. The drugs he processed through the scheme included erectile dysfunction drugs, Schedule II controlled substances such as Adderall and hydrocodone, and Schedule IV controlled substances such as zolpidem, phentermine, diazepam, alprazolam, Tramadol, and carisoprodol.

Mr. Kalita concealed the nature of the drug sales by using merchant payment accounts for travel entities and he created fake travel records to convince the merchant account providers. Specifically, Mr. Kalita and/or his conspirators, would create fake travel itineraries for his customers who purchased his unapproved illegally imported drugs. These actions were done to cover up Mr. Kalita's and his co-conspirators illegal sales of imported misbranded drugs and controlled substances.

FDA sent Mr. Kalita, by certified mail, on May 16, 2025, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Kalita's felony conviction under Federal law for conspiracy to import Schedule II and Schedule IV controlled substances in violation of 21 U.S.C. 963 and one felony count of money laundering conspiracy in violation of 18 U.S.C. 1956(h), was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Kalita illegally imported and introduced misbranded prescription drug products and controlled substances into interstate commerce and laundered the revenues for such importation and introduction for himself and others. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Kalita's offenses and concluded that the offenses warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Kalita of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kalita received the proposal and notice of opportunity for a hearing on May 27, 2025. Mr. Kalita failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Doyal Kalita has been convicted of two felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Kalita is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Kalita is a prohibited act.

Dated: August 14, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15787 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–2025–D–1757]

Oncology Therapeutic Radiopharmaceuticals: Dosage Optimization During Clinical Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 radiopharmaceutical therapies (RPT) for oncology indications during clinical development and prior to submitting a marketing application for a new indication and usage. The guidance provides considerations for RPT dosage optimization in RPT development programs.

DATES: Submit either electronic or written comments on the draft guidance by October 20, 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–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

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