

and requests for reimbursement over the last several years from the SCDD in the Commonwealth of Puerto Rico.

The Puerto Rico SCDD will have up to \$2 million rescinded and proportionately redistributed to the remaining SCDDs. SCDDs that receive FY 2019 reallocated funds will have through the end of FY 2020 to obligate the funds and until the end of FY 2021 to liquidate the funds.

Reallocated funds for the SCDDs must be used according to the terms as outlined in the FY 2019 Notice of Award for each program.

**DATES:** Funds will be reallocated after August 15, 2019 and before September 30, 2019.

**FOR FURTHER INFORMATION CONTACT:**

Allison Cruz, Office of Intellectual and Developmental Disabilities, Administration on Disabilities, Administration for Community Living, 330 C St. SW, Washington, DC 20201. Telephone (202) 795-7408. Email [allison.cruz@acl.hhs.gov](mailto:allison.cruz@acl.hhs.gov). Please note the telephone number is not toll free. This document will be made available in alternative formats upon request. Written correspondence can be sent to Administration for Community Living, U.S. Department of Health and Human Services, 330 C St. SW, Washington, DC 20201.

Dated: July 25, 2019.

**Julie E. Hocker,**

*Commissioner, Administration on Disabilities.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1772]

#### Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations; 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 “Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.” The purpose of this guidance is to assist sponsors in designing appropriate nonclinical

studies before initiation of first-in-human (FIH) trials and through product approval. In addition, this guidance provides recommendations for product labeling, such as duration of contraception to minimize potential risk to a developing embryo or fetus, and recommendations for lactating women to minimize potential risk to a nursing child. This guidance is intended to provide recommendations for nonclinical programs in a unique and challenging area of product development, provide a more consistent approach in nonclinical studies and product labeling, and reduce the conduct of nonclinical studies that are not informative for product use.

**DATES:** The announcement of the guidance is published in the **Federal Register** on August 2, 2019.

**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-2018-D-1772 for “Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.” 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.

- **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.gpo.gov/fdsys/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.

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:** Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993-0002, 301-796-7550; or John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993-0002, 301-796-7550.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a final guidance for industry entitled "Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations." This guidance represents FDA's current thinking on nonclinical studies needed in support of FIH studies and for approval for therapeutic radiopharmaceuticals. *Therapeutic radiopharmaceutical* refers to a pharmaceutical that contains a radionuclide and is used in patients with cancer to treat the disease or palliate tumor-related symptoms (e.g., pain). This guidance discusses the following concepts: Evaluation of toxicities from the ligand; evaluation of radiation toxicities; and information for product labeling as related to reproductive toxicity, genotoxicity, carcinogenicity, contraception, and use in lactating women.

Currently, no FDA or International Council for Harmonisation guidance addresses nonclinical studies in support of FIH trials and approval for radiopharmaceuticals for treatment of cancer. The guidance for industry "Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals" (available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079242.pdf>) describes nonclinical studies to address late radiation toxicity only. This guidance, however, provides further clarification of recommendations made in that guidance for the timing and design of late radiation toxicity studies. This guidance is intended to bring consistency in nonclinical safety assessment and in product labeling for therapeutic radiopharmaceuticals and to

reduce the number of nonclinical studies that are not informative for product use.

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 "Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations." 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. This guidance is not subject to Executive Order 12866.

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These 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. 3501-3520). The collection of information in 21 CFR 312.23(a)(8) for submitting pharmacological and toxicology information has been approved under OMB control number 0910-0014; the collection of information in 21 CFR 201.56 and 201.57 for preparing human prescription drug labeling has been approved under OMB control number 0910-0572; the collection of information in the "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling" final rule has been approved under OMB control number 0910-0624.

**III. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: July 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-0007]

**Prescription Drug User Fee Rates for Fiscal Year 2020**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2020. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products, and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2020.

**FOR FURTHER INFORMATION CONTACT:** Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705-4304, 240-402-4585.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish two different kinds of user fees. Fees are assessed as follows: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products; and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). When specific conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act) or exempt certain prescription drug products from fee (section 736(k) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VI. The base revenue amount for FY 2020 is \$1,001,479,592. The FY 2020 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional full-time equivalent (FTE) positions to support PDUFA VI initiatives. The FY 2020 revenue amount may be adjusted further, if necessary, to provide for