The Quality Metrics Site Visit Program does not supplement or replace a regulatory inspection (*e.g.,* a preapproval inspection, pre-license inspection, or a surveillance inspection).

III. Site Selection

Selection of potential facilities will be based on the priorities developed for CDER and CBER staff training, the facility's current compliance status with FDA, and in consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of FDA; therefore, selection will be based on the availability of funds and resources for the fiscal year. FDA will not provide financial compensation to the pharmaceutical site as part of this program.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site visit program should respond by submitting a proposal directly to Tara Gooen Bizjak or Stephen Ripley (see **FOR FURTHER INFORMATION CONTACT**). To aid in FDA's site selection and planning, your proposal should include the following information:

- A contact person;
- site visit location(s);
- Facility Establishment Identifier and Data Universal Numbering System numbers, as applicable;
- maximum number of FDA staff that can be accommodated during a site visit (maximum of 10),
- a description of the development, history, and ongoing management of the quality metrics program;
- a sample agenda outlining the proposed learning objectives and associated activities for the site visit; and
- preferred dates for a quality metrics site visit.

Proposals submitted without this minimum information will not be considered.

Dated: June 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14006 Filed 6–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1772]

Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' The purpose of this draft guidance is to assist sponsors in designing appropriate nonclinical studies before initiation of first-in-human (FIH) trials and through product approval.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 draft guidance provides recommendations for product labeling, such as duration of contraception to minimize potential risk to a developing embryo/fetus and recommendations for lactating women to minimize potential risk to a nursing infant. This draft guidance intends 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: Submit either electronic or written comments on the draft guidance by August 28, 2018 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–2018–D–1772 for ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations; Draft Guidance for Industry; Availability.'' 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 draft guidance for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' This draft guidance presents FDA's current thinking on nonclinical studies needed to support FIH studies and for approval for therapeutic radiopharmaceuticals. In this draft guidance, the term *therapeutic radiopharmaceutical* refers to a pharmaceutical that contains a radionuclide and is used in patients with cancer for the treatment or for palliation of tumor-related symptoms (*e.g.,* pain). This draft guidance discusses the following concepts: (1) Evaluation of toxicities from the ligand; (2) evaluation of radiation toxicities; and (3) 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 supporting FIH trials and approval for radiopharmaceuticals for treatment of cancer. The guidance for industry entitled ''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 draft guidance provides further clarification of recommendations made in that guidance for the timing and design of late radiation toxicity studies. This draft guidance intends 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 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 nonclinical studies and labeling recommendations for oncology therapeutic radiopharmaceuticals. 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 draft 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; and 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 draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14055 Filed 6–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0793]

Sun Pharmaceutical Industries, Ltd., and Sun Pharma Global FZE; Withdrawal of Approval of Four Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on March 14, 2018. The notice announced the voluntary withdrawal of approval of four abbreviated new drug applications (ANDAs) from two applicants, effective April 13, 2018. In particular, the notice indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical), 2 Independence Way, Princeton, NJ 08540: ANDA 076045, Lorazepam Tablets USP, 0.5 milligram (mg), 1 mg, and 2 mg. Before withdrawal of this ANDA became effective, however, Sun Pharmaceutical informed FDA that it did not want approval of the ANDA withdrawn. Because Sun Pharmaceutical timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 076045 is still in effect.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire