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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' This draft guidance presents FDA's current thinking on nonclinical studies needed to support FIH studies and for approval for therapeutic radiopharmaceuticals. In this draft guidance, the term *therapeutic radiopharmaceutical* refers to a pharmaceutical that contains a radionuclide and is used in patients with cancer for the treatment or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 This draft guidance discusses the following concepts: (1) Evaluation of toxicities from the ligand; (2) evaluation of radiation toxicities; and (3) information for product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

Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Wednesday, March 14, 2018 (83 FR 11208), appearing on page 11208 in FR Doc. 2018–05120, the following correction is made:

1. On page 11208, the entry for ANDA 076045 in the table is removed.

Dated: June 26, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–14050 Filed 6–28–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Faculty Loan Repayment Program, OMB No. 0915–0150—Extension

**AGENCY:** Health Resources and Services Administration, (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than July 30, 2018.

**ADDRESSES:** Submit your comments including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Faculty Loan Repayment Program OMB No. 0915–0150—Extension.

*Abstract:* HRSA administers the Faculty Loan Repayment Program (FLRP). FLRP provides degree-trained health professionals from disadvantaged backgrounds based on environmental and/or economic factors the opportunity to enter into a contract with HHS in exchange for the repayment of qualifying educational loans for a minimum of 2 years of service as a full-time or part-time faculty member at eligible health professions schools.

*Need and Proposed Use of the Information:* The information collected will be used to evaluate applicants' eligibility to participate in FLRP and to monitor FLRP-related activities.

*Likely Respondents:* FLRP applicants and institutions providing employment to the applicants.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Eligible Applications | 111 | 1 | 111 | 1.00 | 111.00 |
| Institution/Loan Repayment Employment Form * | 111 | 1 | 111 | 1.00 | 111.00 |
| Authorization to Release Information Form | 111 | 1 | 111 | 0.25 | 27.75 |
| Total | 333 | | | | 249.75 |

* Respondent for this form is the institution for the applicant.

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

[FR Doc. 2018–13955 Filed 6–28–18; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cell and Molecular Biology.

*Date:* July 11–12, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Amy Kathleen Wernimont, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, Bethesda, MD 20892, 301–827–6427, *amy.wernimont@nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

*Date:* July 13, 2018.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).