

Dated: April 23, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2018-09532 Filed 5-3-18; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2011-N-0075; FDA-2011-N-0015; FDA-2011-N-0076; FDA-2017-N-0932; FDA-2016-N-4487; FDA-2014-N-0345; FDA-2013-N-0523; FDA-2017-N-2428; FDA-2008-N-0312; and FDA-2014-N-1072]

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled “Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals” that appeared in the **Federal Register** of April 9, 2018. The document announced a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The document was published with an

incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Tuesday, April 9, 2018 (83 FR 15152), in FR Doc. 2018-07147, on page 15152, the following correction is made:

1. On page 15152, in the second column, in the first line of the list of docket numbers, “FDA-2014-N-0075” is corrected to read “FDA-2011-N-0075.”

Dated: April 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-09437 Filed 5-3-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-1534]

### Sun Pharmaceutical Industries, Ltd.; Withdrawal of Approval of Three Abbreviated New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of three abbreviated new drug applications (ANDAs) held by Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical). These drug products are no longer marketed, and Sun Pharmaceutical has requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of June 4, 2018.

**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, [Trang.Tran@fda.hhs.gov](mailto:Trang.Tran@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Sun Pharmaceutical has informed FDA that these drug products are no longer marketed and requested that FDA withdraw approval of the applications. Sun Pharmaceutical has also waived its opportunity for a hearing and requested withdrawal of approval under a Consent Decree of Permanent Injunction (Decree) entered in *United States v. Ranbaxy Laboratories, Ltd. et al.*, JFM 12-250 (D. Md.) on January 26, 2012. The Decree specifies that Sun Pharmaceutical must never submit another application to FDA for these withdrawn drugs and must never transfer these ANDAs to a third party.

Application No.	Drug	Applicant
ANDA 065174 .....	Clarithromycin Tablets USP, 250 milligrams (mg) and 500 mg.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 065382 .....	Clarithromycin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250 mg/5 mL.	Do.
ANDA 075747 .....	Ciprofloxacin Tablets USP, Equivalent to (EQ) 250 mg base, EQ 500 mg base, and EQ 750 mg base.	Do.

Therefore, approval of the applications listed in the above table, and all amendments and supplements thereto, is hereby withdrawn as of June 4, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)).

Dated: May 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-09533 Filed 5-3-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-1564]

### Ferndale Laboratories, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of nine abbreviated new drug applications (ANDAs) from multiple applicants. The

holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of June 4, 2018.

**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, [Trang.Tran@fda.hhs.gov](mailto:Trang.Tran@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and

have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have

also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under

§ 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040259 .....	Hydrocortisone Acetate Cream USP, 2.5% .....	Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220.
ANDA 040457 .....	Pyridostigmine Bromide Tablets USP, 60 milligrams (mg) ...	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 061806 .....	Clozapen (cloxacillin sodium) Capsules, Equivalent to (EQ) 250 mg base and EQ 500 mg base.	GlaxoSmithKline, LLC, 5 Crescent Dr., Philadelphia, PA 19112.
ANDA 065453 .....	Vancomycin Hydrochloride (HCl) Capsules USP, EQ 125 mg base and EQ 250 mg base.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 075836 .....	Calcitriol Injection, 1 microgram (mcg)/milliliter (mL) and 2 mcg/mL.	Do.
ANDA 075916 .....	Rimantadine HCl Tablets USP, 100 mg .....	Impax Laboratories, Inc.
ANDA 076731 .....	Glyburide and Metformin HCl Tablets USP, 1.25 mg/250 mg, 2.5 mg/500 mg, and 5 mg/500 mg.	Do.
ANDA 076889 .....	Fluconazole in Sodium Chloride 0.9% Injection, 200 mg/100 mL and 400 mg/200 mL.	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 088572 .....	Pediatric LTA Kit (lidocaine HCl) Solution, 2% .....	Abbott Laboratories, One Abbott Park Rd., Abbott Park, IL 60064.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 4, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 4, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-09534 Filed 5-3-18; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Office of Tribal Self-Governance; Negotiation Cooperative Agreement; Correction of Due Date**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice; Correction of due date.

**SUMMARY:** The Indian Health Service published a notice in the **Federal Register** (FR) on April 17, 2018, for the Negotiation Cooperative Agreement, Funding Announcement Number: HHS-2018-IHS-TSGN-0001. The

Application Due Date has been modified.

**FOR FURTHER INFORMATION CONTACT:** Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the Division of Grants Management main line (301) 443-5204, or Fax: (301)-594-0899.

**Correction**

In the FR notice of April 17, 2018, (FR 2018-07941), the correction is:

**Key Dates:**

Under the heading *Key Dates*, the *Application Due Date* should read as:

- *Application Due Date:* June 18, 2018

The other dates in the *Key Dates* section remain as originally published.

Dated: April 27, 2018.

**Michael D. Weahkee,**

*ADM, Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.*

[FR Doc. 2018-09506 Filed 5-3-18; 8:45 am]

**BILLING CODE 4160-16-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Planning Cooperative Agreement; Correction of Due Date**

**AGENCY:** Office of Tribal Self-Governance, Indian Health Service, HHS.

**ACTION:** Notice; correction of due date.

**SUMMARY:** The Indian Health Service published a notice in the **Federal**

**Register** on April 17, 2018, for the Planning Cooperative Agreement, Funding Announcement Number: HHS-2018-IHS-TSGP-0001. The Application Due Date has been modified.

**FOR FURTHER INFORMATION CONTACT:** Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the Division of Grants Management main line (301) 443-5204, or Fax: (301) 594-0899.

**Correction**

In the FR notice of April 17, 2018, (FR 83 FR 16885), the correction is:

**Key Dates:**

Under the heading *Key Dates*, the *Application Due Date* should read as:

- *Application Due Date:* June 18, 2018

The other dates in the *Key Dates* section remain as originally published.

Dated: April 27, 2018.

**Michael D. Weahkee,**

*Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.*

[FR Doc. 2018-09507 Filed 5-3-18; 8:45 am]

**BILLING CODE 4165-16-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Aging; Notice of Closed Meeting**

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