

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drug products are no longer marketed, and Sun Pharmaceutical has requested that the approval of the applications be withdrawn.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