



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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four abbreviated new drug applications (ANDAs) from two 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 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 075556	Enalapril Maleate Tablets USP, 2.5 milligrams (mg), 5 mg, 10 mg, and 20 mg	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 076045	Lorazepam Tablets USP, 0.5 mg, 1 mg, and 2 mg	Do.
ANDA 078055	Zolpidem Tartrate Tablets USP, 5 mg and 10 mg	Do.
ANDA 090018	Zoledronic Acid for Injection, Equivalent to 4 mg base/vial	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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: March 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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