

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of April 13, 2018.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 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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 13, 2018.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 April 13, 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: March 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-0987]

**Patient-Focused Drug Development on Opioid Use Disorder; Public Meeting; Request for Comments**

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or

we) is announcing the following public meeting entitled “Patient-Focused Drug Development on Opioid Use Disorder.” The purpose of the public meeting is to obtain patients’ perspectives on the impacts of and treatment approaches for opioid use disorder (OUD). This meeting is a part of FDA’s ongoing work aimed at reducing the impact of opioid abuse and addiction.

**DATES:** The public meeting will be held on April 17, 2018, from 10 a.m. to 4 p.m. Submit either electronic or written comments on this public meeting by June 18, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public meeting will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 18, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 18, 2018. Comments received by

mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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: