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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 13, 2018.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*.

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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 13, 2018.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.

[FR Doc. 2018–05120 Filed 3–13–18; 8:45 am]

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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:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–0987 for ''Patient-Focused Drug Development on Opioid Use Disorder; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not 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.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, Fax: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This meeting will provide FDA the opportunity to better understand the patient perspective on the impacts of OUD and on treatment approaches for OUD. OUD is the diagnostic term used for a chronic neurobiological disease characterized by a problematic pattern of opioid use leading to significant impairment or distress. OUD includes signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances for no legitimate medical purpose, or, if another medical condition is present that required opioid treatment, the opioid is used in doses far greater than the amount needed for treatment of that medical condition. FDA is interested in learning patients' perspectives on OUD, including the effects on their health and well-being that have the greatest negative effect on daily life, their experience using prescription medical treatments and other treatments or therapies for OUD, and challenges or barriers to accessing or using medical treatments for OUD.

There are three drugs approved by FDA for the treatment of OUD: Buprenorphine, methadone, and naltrexone. FDA is taking steps to facilitate the development of new medications for the treatment of OUD and new formulations of existing drugs that could better suit patient needs. Promoting wider appropriate use of these safe and effective medications is also the focus of FDA's ongoing work to reduce the scope and magnitude of the opioid crisis.

At the meeting, patients and patient representatives will provide patient perspectives on the symptoms and daily impacts of OUD and on treatment approaches for OUD. The questions that will be asked of patients and patient representatives at the meeting are listed in the following section and organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient representative participants. In addition to input generated through this public meeting, FDA is interested in receiving patient and patient representative input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**). When submitting comments, if you are commenting on behalf of a patient, please indicate that you are doing so and answer the following questions as much as possible from the patient's perspective.

FDA will post the agenda and other meeting materials approximately 5 days before the meeting at: *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm591290.htm.*

II. Topics for Discussion at the Public Meeting

Topic 1: Symptoms and Daily Impacts of OUD That Matter Most to Patients

1. Of all the ways that OUD negatively affects your health and well-being, which effects have the most significant impact on your daily life? Examples of negative effects may include:

• Effects of using opioids, such as confusion, constipation, or other symptoms;

• Effects of opioid withdrawal, such as nausea, diarrhea, or other symptoms;

• Effects of opioid ''cravings;''

• Impacts on ability to function in personal or professional life;

• Emotional or social effects; and

• Other potential effects.

2. How does OUD affect daily life on your best days? On your worst days?

3. How has your OUD changed over time?

4. What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treatment of OUD

1. Are you currently using, or have you used in the past, any prescription medical treatments to treat your OUD? Such treatments may include buprenorphine, methadone, naltrexone, and others that your health care provider has prescribed. If so, please describe your experiences with these treatments.

• How well have these treatments worked for you? How well have they helped address the effects of OUD that are most bothersome to you?

• What are the biggest problems you have faced in using these treatments? Examples may include bothersome side effects, challenges getting the medicines, concern about stigma, and other possible problems.

2. Besides prescription medical treatments, are there other treatments or therapies that you currently use to address your OUD? If so, please describe. How well do these treatments or therapies help address the effects of OUD that are most bothersome to you?

3. Of all treatments, therapies, or other steps that you have taken to address your OUD, what have you found to be most effective in helping you manage your OUD?

4. What are the biggest factors that you take into account when making decisions about seeking out or using treatments for OUD?

5. What specific things would you look for in an ideal treatment for OUD?

6. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for OUD, what factors would you consider when deciding whether or not to participate?

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit *https://www.eventbrite.com/e/public-meeting-for-patient-focused-drug-development-on-opioid-use-disorder-oud-registration-42531194949.* Please register by April 11, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Persons without access to the internet can call 240–402–6525 to register. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by April 11, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 9 a.m.

If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) no later than April 11, 2018.

Panelist Selection: Patients or patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients or patient representatives also will be asked to send *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by April 2, 2018. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Open Public Comment: There will be time allotted during the meeting for open public comment. Sign-up for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting *https://www.eventbrite.com/e/public-meeting-for-patient-focused-drug-development-on-opioid-use-disorder-oud-registration-42531194949.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm591290.htm.*

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–D–0740]

M7(R1): Assessment and Control of Deoxyribonucleic Acid Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''M7(R1): Assessment and Control of Deoxyribonucleic Acid (DNA) Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' This guidance updates and replaces the May 2015 guidance for industry ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' This guidance finalizes the draft guidance ''M7(R1) Addendum to ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,'' issued September 28, 2015 (80 FR 58261).

The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. This M7(R1) document provides guidance on acceptable intakes (AIs), or permissible daily exposures (PDEs), derived for some chemicals that are considered to be mutagens and carcinogens and, are also commonly used in the synthesis of pharmaceuticals or are, useful examples to illustrate the principles for deriving compound-specific intakes described in ICH M7. This document is intended to provide guidance for new drug substances and new drug products during their clinical development and subsequent applications for marketing.

DATES: The announcement of the guidance is published in the **Federal Register** on March 14, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the