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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 13, 2018.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

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA 075556</td>
<td>Enalapril Maleate Tablets USP, 2.5 milligrams (mg), 5 mg, 10 mg, and 20 mg.</td>
<td>Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.</td>
</tr>
<tr>
<td>ANDA 076045</td>
<td>Lorazepam Tablets USP, 0.5 mg, 1 mg, and 2 mg</td>
<td>Do. Do. Do.</td>
</tr>
<tr>
<td>ANDA 078055</td>
<td>Zolpidem Tartrate Tablets USP, 5 mg and 10 mg</td>
<td>Do. Do. Do.</td>
</tr>
</tbody>
</table>

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 13, 2018.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