4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4320]

Sun Pharmaceutical Industries, Inc.; Withdrawal of Approval of 28 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 28 abbreviated new drug applications held by Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical), U.S. Agent for Sun Pharmaceutical Industries Limited, 270 Prospect Plains Rd., Cranbury, NJ 08512. The drug products are no longer marketed, and Sun Pharmaceutical has requested that the approval of the applications be withdrawn.

DATES: [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The applications listed in the table in this document are no longer marketed, and Sun Pharmaceutical has requested that FDA withdraw approval of the applications. The company has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
065007	Cephalexin Capsules USP, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base
065016	Amoxicillin Capsules USP, 250 mg and 500 mg
065021	Amoxicillin Tablets USP (Chewable), 125 mg and 250 mg
065059	Amoxicillin Tablets USP, 500 mg and 875 mg
065060	Amoxicillin Tablets USP (Chewable), 200 mg and 400 mg
065081	Cephalexin for Oral Suspension USP, EQ 125 mg base/5 milliliters (mL) and EQ 250 mg base/5 mL
065082	Cefpodoxime Proxetil for Oral Suspension USP, EQ 50 mg base/5 mL and EQ 100 mg base/5 mL
065083	Cefpodoxime Proxetil Tablets USP, EQ 100 mg base and EQ 200 mg base
065102	Amoxicillin and Clavulanate Potassium Tablets USP, 875 mg/EQ 125 mg base
065109	Amoxicillin and Clavulanate Potassium Tablets USP, 500 mg/EQ 125 mg base
065113	Amoxicillin for Oral Suspension USP, 200 mg/5 mL and 400 mg/5 mL
065115	Cefadroxil for Oral Suspension USP, EQ 125 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 500 mg base/5 mL
065118	Cefuroxime Axetil Tablets USP, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base
065132	Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/EQ 28.5 mg base per 5 mL and 400 mg/EQ 57 mg base per 5 mL
065161	Amoxicillin and Clavulanate Potassium Tablets USP (Chewable), 200 mg/EQ 28.5 mg base and 400 mg/EQ 57 mg base
065207	Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 600 mg/EQ 42.9 mg base per 5 mL
065323	Cefuroxime Axetil for Oral Suspension USP, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL
074975	Acyclovir Capsules USP, 200 mg
074980	Acyclovir Tablets USP, 400 mg and 800 mg
075132	Ranitidine Tablets USP, EQ 75 mg base
075439	Ranitidine Tablets USP, EQ 150 mg base and EQ 300 mg base
076041	Sotret (isotretinoin) Capsules USP, 10 mg, 20 mg, and 40 mg
076285	Simvastatin Tablets USP, 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg
076332	Fluconazole for Oral Suspension, 10 mg/mL and 40 mg/mL
076409	Nefazodone Hydrochloride Tablets USP, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg
076503	Sotret (isotretinoin) Capsules USP, 30 mg
076606	Gabapentin Capsules USP, 100 mg, 300 mg, and 400 mg
076739	Fosinopril Sodium and Hydrochlorothiazide Tablets USP, 10 mg/12.5 mg and 20 mg/12.5 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: December 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-30623 Filed: 12/19/2016 8:45 am; Publication Date: 12/20/2016]