4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3647]

Endo Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 10 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 new drug applications (NDAs) from multiple applicants. The applicants 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: 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 applicants 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
NDA 009165	Delatestryl (testosterone enanthate) Injection, 200 milligrams (mg)/milliliter (mL)	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355
NDA 010417	Xylocaine (lidocaine hydrochloride (HCl)) 4% Topical Solution/Sterile Injection	Fresenius Kabi, USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
NDA 016297	Xylocaine (1.5% lidocaine HCl with dextrose 7.5%) Spinal Injection, 2 mL ampules	Do.
NDA 016724	Norinyl 1+80 (mestranol and norethindrone) 21-Day Tablets, 0.08 mg/1 mg	GD Searle LLC, a subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017
NDA 016725	Norinyl 1+80 (mestranol and norethindrone) 28-Day Tablets, 0.08 mg/1 mg	Do.
NDA 019217	Sodium Chloride 0.9% Injection USP in Plastic Container, 9 mg/mL	ICU Medical, Inc., 600 N. Field Dr., Lake Forest, IL 60045
NDA 019222	Dextrose 5% Injection USP in Plastic Container, 50 mg/mL	Do.
NDA 203098	Testosterone Gel, 2.5 mg/1.25 grams (g), 25 mg/2.5 g, 50 mg/5 g	Perrigo Co., U.S. Agent for Perrigo Israel Pharmaceuticals Ltd., 3490 Quebec Ave. North, Minneapolis, MN 55427
NDA 204031	Xartemis XR (oxycodone HCl and acetaminophen) Extended-Release Tablets, 7.5 mg/325 mg	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042
NDA 205777	Targiniq ER (naloxone HCl and oxycodone HCl) Extended-Release Tablets, 5 mg/10 mg, 10 mg/20 mg, and 20 mg/40 mg	Purdue Pharma, LP, One Stamford Forum, Stamford, CT 06901-3431

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: October 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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