4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0163]

Hospira, Inc., et al.; Withdrawal of Approval of Six Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

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 described 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 040806	Mepivacaine Hydrochloride (HCl) Injection USP, 3%, 30 milligrams (mg)/milliliter (mL)	Hospira, Inc., 275 North Field Dr., Bldg. H, Lake Forest, IL 60045
ANDA 077523	Fluconazole for Oral Suspension, 50 mg/5 mL and 200 mg/5 mL	IVAX Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 078772	Epinephrine and Lidocaine HCl, 0.01 mg/mL; 2% and 0.02 mg/mL; 2%	Hospira, Inc.
ANDA 079138	Articaine HCl and Epinephrine Bitartrate Injection, 4%; EQ 0.017 mg base/1.7 mL, 4%; EQ 0.01 mg base/mL	Do.
ANDA 204236	Norethindrone Acetate Tablets, 5 mg	Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 204421	Tramadol HCl Extended-Release Tablets, 100 mg, 200 mg, and 300 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. 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: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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