4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2702]

Merck Sharp & Dohme Corporation, et al.; Withdrawal of Approval of Four New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 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 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
NDA 005619	Aminohippurate Sodium (PAH) 20% sterile solution Injection, 2 grams in 10 milliliter (mL) vials	Merck Sharp & Dohme Corp., Subsidiary of Merck & Company, Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889
NDA 008506	Hydrocortone (hydrocortisone) Tablets USP, 10 milligrams (mg) and 20 mg	Do.
NDA 011891	Durabolin (nandrolone phenpropionate) Injection, 25 mg/mL and 50 mg/mL	Organon USA, Inc., Subsidiary of Merck & Company, Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 020301	Ortho-Cept (desogestrel and ethinyl estradiol) Tablets USP, 0.15 mg/0.03 mg (21-Day and 28-Day Regimens)	Janssen Pharmaceuticals, Inc., 920 U.S. Hwy. 202, P.O. Box 300, Raritan, NJ 08869-0602

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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