4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1117]

Janssen Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

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 011529	Parafon Forte DSC (chlorzoxazone), Caplets, 500 milligrams (mg)	Janssen Pharmaceuticals, Inc., 1000 Route 202 South, P.O. Box 300, Raritan, NJ 08869
NDA 018029	Ritalin-SR (methylphenidate hydrochloride (HCl)) Extended-Release Tablets, 20 mg	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936
NDA 018082	Depakene (valproic acid) Oral Solution, 250 mg/5 milliliter (mL)	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064
NDA 019579	Terazol 7 (terconazole) Vaginal Cream, 0.4%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 020119	Vumon (teniposide) Injection, 10 mg/mL	HQ Specialty Pharma, 120 Route 17 North, Paramus, NJ 07652
NDA 020388	Navelbine (vinorelbine tartrate) Injection, Equivalent to (EQ) 10 mg/mL base	Pierre Fabre Medicament c/o Pierre Fabre Pharmaceuticals, Inc., 8 Campus Dr., suite 202, Parsippany, NJ 07054
NDA 020741	Prandin (repaglinide) Tablets, 0.5 mg, 1.0 mg, and 2.0 mg	Gemini Laboratories, LLC, 400 Crossing Blvd., 5th Floor, Bridgewater, NJ 08807
NDA 020920	Natrecor (nesiritide) Injection, 1.5 mg/vial	Scios, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 021001	Axert (almotriptan malate) Tablets, EQ 6.25 mg base and EQ 12.5 mg base	Janssen Pharmaceuticals, Inc.
NDA 021203	Tricor (fenofibrate) Tablets, 54 mg and 160 mg	AbbVie Inc.
NDA 021543	Striant (testosterone buccal system) Extended-Release Tablets, 30 mg	Auxilium Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355
NDA 021604	Children's ElixSure IB (ibuprofen) Oral Suspension, 100mg/5 mL	Moberg Pharma North America LLC, 7 East Frederick Place, suite 100, Cedar Knolls, NJ 07927
NDA 021611	Opana (oxymorphone HCl) Tablets, 5mg and 10mg	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355
NDA 022321	Embeda (morphine sulfate and naltrexone HCl) Extended-Release Capsules, 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg, and 100 mg/4 mg	Alpharma Pharmaceuticals, LLC, 235 East 42nd St., New York, NY 10017
NDA 022510	Abstral (fentanyl) Sublingual Tablets,100 micrograms (mcg), 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg	Sentynl Therapeutics, Inc., 420 Stevens Ave., suite 200, Solana Beach, CA 92075
NDA 050641	Monodox (doxycycline monohydrate) Capsules, EQ 50mg base, EQ 75mg base, and EQ 100mg base	Aqua Pharmaceuticals, LLC, 707 Eagleview Blvd., suite 200, Exton, PA 19341

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 and dosage forms 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: May 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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