4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1071]

Allergan Sales, LLC, et al.; Withdrawal of Approval of 18 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 18 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 007409	Bentyl (dicyclomine hydrochloride (HCl)) Capsules, 10 milligram (mg) Bentyl (dicyclomine HCl) Tablets, 20 mg	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 013625	Norinyl 1 + 50 (norethindrone and mestranol) Tablets, 0.05 mg/1 mg Norinyl (norethindrone and mestranol) Tablets, 0.1 mg/2 mg	Actavis Laboratories UT, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 145 Brandywine Pkwy., West Chester, PA 19380
NDA 014169	Dendrid (idoxuridine) Ophthalmic Solution, 0.1%	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134
NDA 019404	Ocufen (flurbiprofen sodium) Ophthalmic Solution, 0.03%	Allergan, Inc., 2525 Dupont Dr., Irvine, CA 92612
NDA 019784	Ibuprofen Oral Suspension, 100 mg/5 milliliters (mL)	Abbott Laboratories Established Pharmaceuticals Products Division, 200 Abbott Park Rd., Abbott Park, IL 60064
NDA 020010	Lotrisone (betamethasone dipropionate and clotrimazole) Lotion, Equivalent to (EQ) 0.05% base/1%	Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., 1 Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889
NDA 020098	Mivacron (mivacurium chloride) Solution, EQ 2 mg base/mL, EQ 10 mg base/5 mL, and EQ 20 mg base/10 mL Mivacron in Dextrose 5% in plastic container (mivacurium chloride) Injectable, EQ 0.5 mg base/mL and EQ 50 mg base/100 mL	AbbVie, Inc., 1 N. Waukegan Rd., North Chicago, IL 60064
NDA 020412	Zerit (stavudine) Capsules, 5mg, 15 mg, 20 mg, 30 mg, and 40 mg	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543
NDA 020509	Gemzar (gemcitabine HCl) Injection, EQ 200 mg base and EQ 1 gram (g) base	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 020696	Antizol (fomepizole) Injection, 1.5 g/1.5 mL	Par Sterile Products, LLC, 6 Ram Ridge Rd., Chestnut Ridge, NY 10977
NDA 020705	Rescriptor (delavirdine mesylate) Tablets, 100 mg and 200 mg	ViiV Healthcare Co., 5 Moore Dr., Research Triangle Park, NC 27709
NDA 021114	Betaxon (levobetaxolol HCl) Ophthalmic Suspension, EQ 0.5% base	Alcon Laboratories, Inc.
NDA 021199	Quixin (levofloxacin) Ophthalmic Solution, 0.5%	Santen Inc., 6401 Hollis St., Suite 125, Emeryville, CA 94608
NDA 021571	Iquix (levofloxacin) Ophthalmic Solution, 1.5%	Do.
NDA 050704	DaunoXome (daunorubicin citrate liposome injection), EQ 2 mg base/mL	Galen Limited, 25 Fretz Rd., Souderton, PA 18964

NDA 204736	AcipHex Sprinkle (rabeprazole sodium) Delayed Release Capsules, 5 mg and 10 mg	Aytu BioScience Inc., 373 Inverness Parkway, Suite 206, Englewood, CO 80112
NDA 205060	Epanova (omega-3-carboxylic acids) Capsules, 1 gram (1 g contains at least 850 mg of polyunsaturated fatty acids)	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803
NDA 206843	Daklinza (daclatasvir dihydrochloride) Tablets, EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base	Bristol-Myers Squibb Co.

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: October 25, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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