4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0478]

Sebela Ireland, Ltd. et al.; Withdrawal of Approval of 24 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 24 abbreviated new drug applications (ANDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

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 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 040398	MiCort-HC (hydrocortisone acetate) Cream USP, 2%	Sebela Ireland, Ltd., c/o Sebela Pharmaceuticals, Inc., 645 Hembree Parkway, Suite 1, Roswell, GA 30076
ANDA 071893	Acetohexamide Tablets, 250 milligrams (mg)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 071894	Acetohexamide Tablets, 500 mg	Do.
ANDA 073143	Cyclobenzaprine Hydrochloride (HCl) Tablets USP, 10 mg	Do.
ANDA 074576	Captopril Tablets USP, 12.5 mg, 25 mg, 50 mg, and 100 mg	Do.
ANDA 076607	Quinapril Tablets USP, Equivalent to (EQ) 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 076786	Donepezil HCl Tablets USP, 5 mg and 10 mg	Do.
ANDA 077483	Benazepril HCl and Hydrochlorothiazide Tablets, 5 mg/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg	Do.
ANDA 078502	Eliphos (calcium acetate) Tablets USP, 667 mg	Cypress Pharmaceutical, Inc., 10 North Park Pl., Suite 201, Morristown, NJ 07960
ANDA 081019	Chlorzoxazone Tablets USP, 500 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083821	Brompheniramine Maleate Injection, 10 mg/milliliter (mL)	Do.
ANDA 084408	Bethanechol Chloride Tablets USP, 10 mg	Do.
ANDA 084441	Bethanechol Chloride Tablets USP, 25 mg	Do.
ANDA 085283	Theolair (theophylline) Tablets, 125 mg and 250 mg	3M Drug Delivery Systems, 3M Center, Bldg. 275-3E-02, 2510 Conway Ave., St. Paul, MN 55144
ANDA 085738	Betamethasone Sodium Phosphate Injection, EQ 3 mg base/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087444	Bethanechol Chloride Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087792	Fluorouracil Injection USP, 50 mg/mL	Spectrum Pharmaceuticals, Inc., 157 Technology Dr., Irvine, CA 92618
ANDA 087978	Diphenhydramine HCl Capsules, 50 mg	LNK International, Inc., 145 Ricefield Ln.,

Application No.	Drug	Applicant
		Hauppauge, NY 11788
ANDA 090417	Carbinoxamine Maleate Tablets USP, 4 mg	Cypress Pharmaceutical, Inc.
ANDA 090418	Carbinoxamine Maleate Oral Solution, 4 mg/5 mL	Do.
ANDA 090468	Zyfrel (acetaminophen and hydrocodone bitartrate) Oral Solution, 325 mg/7.5 mg per 15 mL	Do.
ANDA 091034	Dorzolamide HCl Ophthalmic Solution USP, EQ 2% base	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242
ANDA 200794	Pantoprazole Sodium Delayed-Release Tablets USP, EQ 20 mg base and EQ 40 mg base	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc.
ANDA 206438	Hydrocodone Bitartrate and Chlorpheniramine Maleate Oral Solution, 5 mg/4 mg per 5 mL	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852

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: February 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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