4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0002]

Delcor Asset Corp. et al.; Withdrawal of Approval of 22 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 22 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 table 1 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.

Table 1.--ANDAs for Which FDA is Withdrawing Approval

Application No.	Drug	Applicant
ANDA 060577	Mycostatin (nystatin) Vaginal	Delcor Asset Corp., 411 South State St.,

Application No.	Drug	Applicant
	Tablets, 100,000 units	Suite E-100, Newtown, PA 18940
ANDA 063302	Cefamandole Nafate for Injection	ACS Dobfar SpA, c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07653
ANDA 070462	Diazepam Tablets USP, 2 milligrams (mg)	Virtus Pharmaceuticals, 12 Penns Trail, Newtown, PA 18940
ANDA 070463	Diazepam Tablets USP, 5 mg	Do.
ANDA 070998	Potassium Chloride Extended-Release Tablets, 8 milliequivalents (mEq)	Future Pak, Ltd., 28115 Lakeview Dr., Wixom, MI 48393
ANDA 070999	Potassium Chloride Extended-Release Tablets, 10 mEq	Do.
ANDA 075375	Diltiazem Hydrochloride (HCl) Injection, 5 mg/milliliter (mL)	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 076911	Clorazepate Dipotassium Tablets USP, 3.75 mg, 7.5 mg, and 15 mg	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 077102	Calcitriol Injection, 0.001 mg/mL	Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd., Suite 450, Schaumburg, IL 60195
ANDA 084656	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 087977	Diphenhydramine HCl Capsules, 25 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788
ANDA 088676	Methylprednisolone Sodium Succinate for Injection USP, Equivalent to 40 mg base/vial	LyphoMed, Division of Fujisawa USA, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160
ANDA 089080	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207
ANDA 089183	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg	Superpharm Corp., 1769 Fifth Ave., Bayshore, NY 11706
ANDA 089253	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Do.
ANDA 089219	Procainamide HCl Capsules USP, 250 mg, 375 mg, and 500 mg	IDT Australia, Ltd., c/o Facet Life Sciences, Inc., 6122 Stone Wolfe Dr., Glen Carbon, IL 62034
ANDA 089254	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg	Do.
ANDA 089369	Procainamide HCl Extended-Release Tablets USP, 250 mg, 500 mg,	Do.

Application No.	Drug	Applicant
	and 750 mg	
ANDA 089481	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg	American Therapeutics, Inc., 75 Carlough Rd., Bohemia, NY 11716
ANDA 089482	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Do.
ANDA 089483	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg	Do.
ANDA 206711	Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg	Ajanta Pharma, Ltd., c/o Ajanta Pharma USA, Inc., One Grande Commons, 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807

Therefore, approval of the applications listed in table 1, 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 table 1 that are in inventory on the date that this notice becomes effective (see the DATES section) 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: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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