4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5550]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 23 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 23 abbreviated new drug applications (ANDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

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 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

Application No.	Drug	Applicant
ANDA 040448	Phentermine Hydrochloride (HCl) Capsules USP, 30 milligrams (mg)	Elite Laboratories, Inc., 165 Ludlow Ave., Northvale, NJ 07647
ANDA 060272	E-Mycin (erythromycin) Delayed-Release Tablets USP, 250 mg and 333 mg	Arbor Pharmaceuticals, LLC, 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328
ANDA 061639	E.E.S. 200 (erythromycin ethylsuccinate) for Oral Suspension, Equivalent to (EQ) 200 mg base/5 milliliters (mL).E.E.S. 400 (erythromycin ethylsuccinate) for Oral Suspension, EQ 400 mg base/5 mL	Do.
ANDA 062290	EryDerm (erythromycin) Topical Solution USP, 2%	Arbor Pharmaceuticals, LLC
ANDA 062304	Pediamycin (erythromycin ethylsuccinate) Oral Suspension USP, EQ 200 mg base/5 mL Pediamycin 400 (erythromycin ethylsuccinate) Oral Suspension USP, EQ 400 mg base/5 mL	Do.
ANDA 062659	Claforan ADD-Vantage (cefotaxime) for Injection USP, EQ 1 gram (g) base/vial and EQ 2 g base/vial	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807
ANDA 070347	Hydro-Ride (amiloride HCl and hydrochlorothiazide) Tablets, EQ 5 mg Anhydrous/50 mg	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977
ANDA 071142	Clonidine HCl and Chlorthalidone Tablets USP, 0.3 mg/15 mg	Do.
ANDA 071178	Clonidine HCl and Chlorthalidone Tablets USP, 0.2 mg/15 mg	Do.
ANDA 071179	Clonidine HCl and Chlorthalidone Tablets USP, 0.1 mg/15 mg	Do.
ANDA 073191	Triamterene and Hydrochlorothiazide Capsules USP, 50 mg/25 mg	CASI Pharmaceuticals, Inc., c/o Target Health, Inc., 261 Madison Ave., 24th Floor, New York, NY 10016
ANDA 073416	E-Z Scrub (chlorhexidine gluconate) Sponge, 4%	Becton, Dickinson and Co., 9450 South State St., Sandy, UT 84070
ANDA 076075	Econazole Nitrate Cream, 1%	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.
ANDA 076192	Ribavirin Capsules USP, 200 mg	Do.
ANDA 076514	Midodrine HCl Tablets USP, 2.5 mg, 5 mg, and 10 mg	Do.
ANDA 078665	Next Choice (levonorgestrel) Tablets, 0.75 mg	Foundation Consumer Healthcare, LLC, 1190 Omega Dr., Pittsburgh, PA 15205
ANDA 086809	Spironolactone Tablets USP, 25 mg	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.

Application No.	Drug	Applicant
ANDA 087143	Acetasol HC (hydrocortisone and acetic acid) Otic Solution USP, 1% and 2%	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
ANDA 088432	Meperidine HCl Injection USP, 10 mg/mL	ICU Medical, Inc., 600 North Field Dr., Lake Forest, IL 60045
ANDA 090288	Naratriptan Tablets USP, EQ 1 mg base and EQ 2.5 mg base	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.
ANDA 091597	Gemcitabine for Injection USP, EQ 200 mg base/vial and EQ 1 g base/vial	Sagent Pharmaceuticals, Inc., 1901 North Roselle Rd., Schaumburg, IL 60195
ANDA 200670	Next Choice One Dose (levonorgestrel) Tablets, 1.5 mg	Foundation Consumer Healthcare, LLC
ANDA 203384	Epinastine HCl Ophthalmic Solution, 0.05%	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.

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 or products 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: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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