



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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on January 8, 2020. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of February 7, 2020. The document indicated that FDA was withdrawing approval of the following seven ANDAs after receiving a withdrawal request from CASI Pharmaceuticals, Inc., c/o Target Health, Inc., 261 Madison Ave., 24th Floor, New York, NY 10016: ANDA 073191, Triamterene and Hydrochlorothiazide Capsules USP, 50 milligrams (mg)/25 mg; ANDA 076075, Econazole Nitrate Cream, 1%; ANDA 076192, Ribavirin Capsules USP, 200 mg; ANDA 076514, Midodrine Hydrochloride (HCl) Tablets USP, 2.5 mg, 5 mg, and 10 mg; ANDA 086809, Spironolactone Tablets USP, 25 mg; ANDA 090288, Naratriptan Tablets USP, Equivalent to (EQ) 1 mg base and EQ 2.5 mg base; and ANDA 203384, Epinastine HCl Ophthalmic Solution, 0.05%. Before FDA withdrew the approval of these ANDAs, CASI Pharmaceuticals, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because CASI Pharmaceuticals, Inc., timely requested that approval of these ANDAs not be withdrawn, the

approval of ANDAs 073191, 076075, 076192, 076514, 086809, 090288, and 203384 is still in effect.

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: In the *Federal Register* of Wednesday, January 8, 2020 (85 FR 909), in FR Doc. 2020-00076, on page 909, the following correction is made:

1. On pages 909 and 910, in the table, the entries for ANDAs 073191, 076075, 076192, 076514, 086809, 090288, and 203384 are removed.

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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