ELITE PHARMACEUTICALS INC /DE/
Form 8-K
June 06, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

May 31, 2011

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of Company as specified in its charter)

Delaware	001-15697	22-3542636
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

165 Ludlow Avenue, Northvale, New Jersey 07647

(Address of principal executive offices)

(201) 750-2646

(Company’s telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Company under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On May 31, 2011, the Company received a letter from the US Food and Drug Administration (FDA) responding to a Changes Being Effected in 30 Days ("CBE 30") supplement filed by the Company with the agency to change the manufacturing and packaging location of the Hydromorphone Hydrochloride Tablets USP, 8 mg ANDA purchased from Mikah Pharma. The letter from the FDA informed the Company that the agency has reclassified the application as a prior approval supplemental application which will delay the commercialization.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits
a) Not applicable.
b) Not applicable.
c) Not applicable.
d) Exhibits

Exhibit No.	Exhibit
99.1	Press Release dated June 6, 2011

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: June 6, 2011

ELITE PHARMACEUTICALS, INC.

By: /s/ Chris Dick
Name: Chris Dick
Title: President & Chief Operating Officer