CARACO PHARMACEUTICAL LABORATORIES LTD
Form 8-K
November 03, 2008

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

October 31, 2008

(Date of report)

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(Exact name of registrant as specified in its charter)

Michigan	0-24676	38-2505723
(State or other jurisdiction of incorporation)	(Commission file number)	(I.R.S. employer identification no.)

1150 Elijah McCoy Drive, Detroit, Michigan 48202

(Address of principal executive offices)

(313) 871-8400

(Registrant’s telephone number, including area code)

Not Applicable

(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 registrant under any of the following provisions:

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

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 140.14a-12)

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

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

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Item 8.01 Other Events

On October 31, 2008, the Company received a warning letter from the FDA. The letter was issued as a follow up to the last FDA inspection of our manufacturing facility in Detroit, Michigan which was initiated in May 2008. As previously disclosed, a Form 483 notice was issued in June 2008 following this inspection. We had responded to all the observations made in the Form 483 within thirty days thereof, and corrective actions were taken and substantially completed. Subsequent letters noting additional improvements were also provided to the FDA similar to what we have done in previous correspondence with the FDA. The observations set forth in the warning letter include, among other things, the inadequate and untimely investigation by our quality control unit of certain incidents at our facility contrary to our standard operating procedures. The FDA considered some of its observations to be repeat observations. We believe that the full warning letter, listing all of the observations, will be posted by the FDA shortly on its website at www.fda.gov.

Until our responses to the observations have been clarified and explanations provided to the satisfaction of the FDA, the FDA may in the near term withhold approval of pending new drug applications listing our facility as the manufacturer.

We intend to respond promptly and timely to the FDA within fifteen business days. We are committed to working cooperatively and expeditiously with the FDA to resolve the matters indicated in its letter.

SIGNATURES

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

Date: November 3, 2008 By: /s/ Daniel H. Movens
Daniel H. Movens

Chief Executive Officer