

CARACO PHARMACEUTICAL LABORATORIES LTD

Form 8-K

December 29, 2005

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

December 28, 2005
(Date of report)

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction
of incorporation)

0-24676
(Commission file number)

38-2505723
(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:

- ☐ 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 140.14a-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))
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Item 8.01 Other Events

On December 27, 2005, the U.S. Food and Drug Administration granted tentative approval of the Company's ANDA for Carvedilol 3.125 mg tablets. Final approval of this product is anticipated subsequent to the expiry of patent protection in February 2016. Caraco's Carvedilol 3.125 mg tablets is the generic equivalent of GlaxoSmithkline's Coreg® 3.125mg, which is indicated for the treatment of mild to severe heart failure of ischemic or cardiomyopathic origin. It is also indicated to reduce cardiovascular mortality and for the management of essential hypertension.

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: December 29, 2005

By: /s/ Daniel H. Movens

Daniel H. Movens
Chief Executive Officer
