

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
July 06, 2005

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

**Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934**

For the month of July 2005

Commission File Number 0-16174

- 1 -

Teva Pharmaceutical Industries Limited

(Translation of registrant's name into English)

5 Basel Street, P.O. Box 3190

Petach Tikva 49131 Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):
82- _____

Teva Pharmaceutical Industries Ltd.

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Teva Pharmaceutical Industries Ltd.

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TEVA COMMENTS ON FDA LETTER REGARDING PRAVASTATIN EXCLUSIVITY

Jerusalem, Israel, July 6, 2005 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has received a letter from the U.S. Food and Drug Administration ("FDA") concerning the 180-day exclusivity period applicable to ANDAs for generic Pravastatin Sodium Tablets 10 mg., 20 mg., 40 mg., and 80 mg, the generic equivalents of Pravachol[®]. The FDA has decided that any 180-day exclusivity period arising from U.S. Patents Nos. 5,030,447, 5,180,589, and 5,622,985 began to run on August 22, 2004, the date the order dismissing a declaratory judgment action suit by Apotex Inc. against Bristol-Myers Squibb Co. became final. This decision is based upon the FDA's interpretation of prior case law.

Teva strongly disagrees with the FDA's interpretation and believes that there are significant distinctions between the facts surrounding the Pravastatin dismissal and the prior case law. Teva will immediately pursue legal action to obtain reversal of the decision. As the first applicant to file an ANDA under Paragraph IV of Hatch-Waxman Act, Teva continues to believe that it is entitled to 180 days of marketing exclusivity for generic Pravastatin Sodium Tablets 10 mg., 20 mg., and 40 mg.

Mr. Israel Makov, Teva's President and CEO said: "Although we are disappointed by this ruling which we intend to strongly oppose, we are confident that Teva's portfolio of new generic products will contribute to significant growth during 2006 and 2007, a period during which we expect to launch approximately 80 generic products in the U.S."

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva's sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell or license their own generic products (so called "authorized generics") or successfully extend the exclusivity period of their branded products, the effects of competition on Copaxone® sales, including potential competition from the expected launch of Tysabri®/Antegren®, Teva's ability to rapidly integrate the operations of acquired businesses, including its acquisition of Sicor Inc., regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to completion of appellate litigation, including that relating to Neurontin, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva's ability to successfully identify, consummate and integrate acquisitions, exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations outside the United States that may be adversely affected by terrorism or major hostilities, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

Teva Pharmaceutical Industries Ltd.

Web Site: www.tevapharm.com

SIGNATURES

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, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Dan Suesskind

Name: Dan Suesskind

Title: Chief Financial Officer

Date: July 6, 2005

