

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
July 06, 2004

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 2004

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. Web Site www.tevapharm.com

Contact: Dan Suesskind

Chief Financial Officer

Teva Pharmaceutical Industries Ltd.

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Bill Fletcher

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-8800

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TEVA RECEIVES APPROVABLE LETTER FOR AGILECT[®] (rasagiline)

Jerusalem, Israel, July 5, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has received an approvable letter from the U.S. Food and Drug Administration (FDA) for once-daily AGILECT[®] (rasagiline mesylate) as a treatment for Parkinson's disease (PD) as initial monotherapy in early PD patients and as adjunct therapy to levodopa in moderate-to-advanced stages of the disease. Following the approvable letter, Teva will work together with the FDA to complete the process of receiving final approval as soon as possible.

Israel Makov, President and CEO of Teva commented, "We are very pleased to receive this approvable letter, which is a major regulatory milestone in the approval process of AGILECT[®]". Mr. Makov added, "Today represents another important step towards Teva being able to offer a new treatment option to the many patients who currently suffer from

Parkinson's disease in the United States."

Teva Neuroscience, Inc. and Eisai Inc. will co-promote AGILECT[®] in the United States once approved by the FDA and Teva and H. Lundbeck A/S will co-promote the product in Europe, once approved there.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 pharmaceutical companies in the world. The company develops, manufactures, and markets generic and branded human pharmaceuticals and active pharmaceutical ingredients. Close to 90 percent of Teva's sales are in North America and Europe. Teva's innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

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 current 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 their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, including its recent acquisition of Sicor Inc., the availability of product liability coverage in the current insurance market, 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 and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, 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.

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 05, 2004

