TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
June 17, 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 June 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 X 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 X

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.

(011) 972-2-589-2840

Bill Fletcher

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-8800

Dorit Meltzer

Director, Investor Relations

Teva Pharmaceutical Industries Ltd.

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TEVA ANNOUNCES APPROVAL OF ADENOSINE INJECTION

Jerusalem, Israel, June 16, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration has granted final approval for the Company`s ANDA for Adenosine Injection USP, 3 mg/mL, which was submitted by the Company`s subsidiary SICOR Inc. Shipment of this

product, which has been approved in 2 mL and 4 mL vials, is expected to begin immediately.

Teva`s Adenosine Injection USP is the generic equivalent of Fujisawa`s Adenocard&reg Injection. This product is indicated for conversion to sinus rhythm of paroxysmal supraventricular tachycardia (PSVT), including that associated with accessory bypass tracts (Wolff-Parkinson-White Syndrome).

The brand product has annual sales of approximately $13 million.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 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.

afe 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 forwardlooking

statement, whether as a result of new information, future developments or otherwise.

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Teva and AVENTIS ANNOUNCE THAT COPAXONE &reg PRE-FILLED SYRINGE IS NOW AVAILABLE ALSO IN EUROPE

Combined with COPAXONE&reg sustained effect, the pre-filled syringe form significantly improves quality of life for patients with Multiple Sclerosis

Jerusalem, Israel, June 17, 2004, Teva Pharmaceutical Industries Ltd. and Aventis Pharma today announced that the Multiple Sclerosis (MS) therapy COPAXONE&reg (glatiramer acetate injection) is now available also in Europe in a pre-filled, ready-to-use syringe (PFS). For physicians, nurses and pharmacists, compliance and adherence to treatment are among the most important factors in any therapy. With COPAXONE&reg PFS, injection will be faster and more convenient. No mixing or preparation is required, and fewer supplies are needed, ensuring increased accuracy, better compliance, and reduced risk of contamination.

COPAXONE&reg PFS contains exactly the same active ingredient and dose as the lyophilized form of COPAXONE&reg, but in a more convenient and easier-to-use injectable form. "The new pre-filled syringe is about meeting patients' needs for a treatment that is convenient, consistent and complete," said Israel Makov, President and CEO of Teva. *"The COPAXONE&reg PFS offers important and improved benefits for patients who already use our product, and will increase COPAXONE&reg*'s appeal to additional MS patients throughout Europe. This is another step towards making COPAXONE&reg the drug of choice for MS patients in the European market."

"COPAXONE&reg has demonstrated sustained effect on both reducing relapse rate and preserving physical function. COPAXONE&reg PFS provides the same efficacy as the original presentation. The new form makes it easier for patients with MS to focus more on their lives and less on their therapy," said Laszlo Szapary, Senior Vice President of Aventis Pharma.

COPAXONE&reg PFS was approved through the Mutual Recognition Procedure on January 13th 2004. The first country to launch COPAXONE&reg PFS will be Germany, and the rest of the European Union will follow shortly. COPAXONE&reg PFS will replace the existing form according to the specific needs of each country. To date, COPAXONE&reg PFS was successfully launched in US, Canada, and Israel where virtually all patients have switched from the lyophilized to the PFS presentation. These patients are now able to enjoy the benefits of increased comfort and convenience together with COPAXONE&reg's efficacy.

COPAXONE&reg PFS may be stored at room temperature for up to 7 days and will be used with a new simple-to-use **auto***ject* 2&reg device. The combination of the new pre-filled syringe and **auto***ject* 2&reg simplifies the injection process for patients and makes administration more manageable.

COPAXONE&reg is one of the fastest growing MS therapies worldwide. More than 80,000 patients globally have been receiving treatment with COPAXONE&reg. In the United States, COPAXONE&reg has a market share of 29 percent of total prescriptions (IMS April 2004), and is growing faster than the rate of the MS market.

COPAXONE&reg is now approved in 42 countries worldwide, including the U.S., Canada, Australia, Israel, and all the European countries. In Europe, COPAXONE&reg is marketed by Teva Pharmaceutical Industries Ltd., and Aventis Pharma. In North America, COPAXONE&reg is marketed by Teva Neuroscience Inc.

About Teva

Teva Pharmaceutical Industries Ltd., (NASDAQ: TEVA) 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. For more information, please visit: www.tevapharm.com

About Aventis

Aventis is dedicated to treating and preventing disease by discovering and developing innovative prescription drugs and human vaccines. In 2003, Aventis generated sales of Euro 16.79 billion, invested Euro 2.86 billion in research and development and employed approximately 69,000 people in its core business. Aventis corporate headquarters are in Strasbourg, France. For more information, please visit: www.aventis.com.

For Teva

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.

For Aventis

Statements in this news release containing projections or estimates of revenues, income, earnings per share, capital expenditures, capital structure, or other financial items; plans and objectives relating to future operations, products, or services; future economic performance; or assumptions underlying or relating to any such statements, are forward-looking statements subject to risks and uncertainties. Actual results could differ materially depending on factors such as the timing and effects of regulatory actions, the results of clinical trials, the company`s relative success developing and gaining market acceptance for new products, the outcome of significant litigation, and the effectiveness of patent protection. Additional information regarding risks and uncertainties is set forth in the current Annual Report on Form 20-F of Aventis on file with the Securities and Exchange Commission and in the current Annual Report -"Document de Référence"- on file with the "Authorité des marchés financiers" in France.

Pursuant to Article 7 of the COB Regulation no. 2002-04, this press release was transmitted to the Authorité des marchés financiers before its release.

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: June 17, 2004