TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
January 31, 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 January 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 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

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Contact: Dan Suesskind

Chief Financial Officer

Teva Pharmaceutical Industries Ltd.

(011) 972-2-589-2840

George Barrett

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-3030

Dorit Meltzer

Director, Investor Relations

Teva Pharmaceutical Industries Ltd.

(011) 972-3-926-7554

TEVA ANNOUNCES APPROVAL OF GLYBURIDE/METFORMIN HCl TABLETS

Jerusalem, Israel, January 28, 2005 - 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 Glyburide and Metformin HCl Tablets, 1.25 mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg. Shipment of this product is expected to begin shortly.

Teva`s Glyburide and Metformin HCl Tablets are the AB-rated generic equivalent of Bristol-Myers Squibb`s Glucovance&reg Tablets, a product indicated as an adjunct to diet and exercise in the treatment of type 2 diabetes.

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.

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&reg sales, including potential competition from the expected launch of Tysabri&reg/Antegren&reg, 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.

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TEVA ANNOUNCES COURT OF APPEALS GRANTS FAVORABLE RULING ON ONCE-A-WEEK VERSION OF FOSAMAX&reg

Jerusalem, Israel, January 28, 2005 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the United States Court of Appeals for the Federal Circuit has found that U.S. Patent No. 5,994,329 is invalid and, accordingly, has reversed and vacated an August 2003 ruling by the U.S. District Court in Wilmington, Delaware which had upheld the validity of the patent. The patent is listed in the U.S. Food and Drug Admnistration`s Orange Book for Merck & Co.'s Fosamax&reg, 35 mg and 70 mg, for which Teva has filed an Abbreviated New Drug Application to market a generic version of Fosamax&reg.

Teva believes that as a result of today`s ruling, its ANDA will be eligible for Final Approval in February 2008 when U.S. Patent No. 4,621,077 expires.

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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: January 28, 2005