

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

December 01, 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 November 2005

Commission File Number 0-16174



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**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):  
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Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://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

Liraz Kalif / Kevin Mannix

Investor Relations

(011) 972-3-926-7554 / (215) 591-8912

## **TEVA ANNOUNCES TENTATIVE APPROVAL OF ZALEPLON CAPSULES**

**Jerusalem, Israel, November 30, 2005** - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration has granted tentative approval for the Company's ANDA for Zaleplon Capsules, 5 mg and 10 mg.

Upon final approval, Teva's Zaleplon Capsules will be the AB-rated generic equivalent of Jones Pharma Inc.'s Sonata<sup>®</sup> Capsules, a product indicated for short term treatment of insomnia. The brand product has annual sales of approximately \$121 million.

Teva is currently in patent litigation concerning this product in the U.S. District Court for the District of New Jersey. King Pharmaceuticals brought suit against Teva in August 2005 involving Teva's paragraph IV certification to U.S. Patent No. 4,626,538.

Final approval is expected upon the earlier of a favorable decision in the case or expiry of the mandatory stay of approval in December 2007.

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 whether and when the proposed acquisition of IVAX Corporation will be consummated and the terms of any conditions imposed in connection with such closing, the terms and conditions of the financing utilized by Teva for the IVAX acquisition, Teva's ability to rapidly integrate IVAX's operations and achieve expected synergies, 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 under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic products, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final court decision, including that relating to the generic versions of Neurontin® and Allegra®, the effects of competition on Copaxone® sales, 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](http://www.tevapharm.com)

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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: November 30, 2005

