

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

November 01, 2002

Teva Pharmaceutical Industries Ltd. Web Site [www.tevapharm.com](http://www.tevapharm.com)

**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 October 2002

Commission File Number 0-16174

**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):

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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-

Contact: Dan Suesskind

Chief Financial Officer  
Teva Pharmaceutical Industries Ltd  
(011) 972-2-589-2840

Bill Fletcher  
President and CEO  
Teva North America.  
(215) 591-8800

**FOR IMMEDIATE RELEASE**

Dorit Meltzer  
Director, Investor Relations  
Teva Pharmaceutical Industries Ltd.  
(011) 972-3-926-7554

**TEVA ANNOUNCES APPROVAL OF GENERIC VERSION OF AUGMENTIN<sup>(R)</sup>**

Jerusalem, Israel, October 30, 2002 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA)

announced today that the U. S. Food and Drug Administration has approved the Company's ANDA for Amoxicillin and Clavulanate Potassium Tablets, the generic version of GlaxoSmithKline's Augmentin<sup>(R)</sup> 875 mg/125 mg. Teva has immediately begun making the necessary preparations to market this product. Approval of the ANDA for the 500 mg/125 mg strength is expected shortly.

Augmentin<sup>(R)</sup> is a widely administered broad spectrum antibiotic. Annual sales of the 875 mg/125 mg strength in the US are approximately \$830 million.

Today's approval follows an earlier ruling by a federal judge, which invalidated seven GlaxoSmithKline patents related to this product. GlaxoSmithKline has appealed the decision.

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Commenting on today's approval, Israel Makov, President and CEO of Teva Pharmaceuticals said "We are delighted to receive final approval of our generic version of Augmentin<sup>(R)</sup> and look forward to helping American consumers get affordable access to this important drug. We expect that this will quickly become one of Teva's most important products."

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 35 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Over 80% of Teva's sales are in North America and Europe. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients.

*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, 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 ("FDA") 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 ("SEC"). 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 PROVIDES UPDATED OUTLOOK ON 4<sup>th</sup> QUARTER 2002 EARNINGS IN LIGHT OF  
AMOX/CLAV ANDA APPROVAL**

Jerusalem, Israel, October 30, 2002 -- Teva Pharmaceutical Industries Ltd. (Nasdaq:TEVA) provided new financial guidance in light of its receipt of U.S. Food and Drug Administration approval of its ANDA for Amoxicillin and Clavulanate Potassium Tablets, the generic version of GlaxoSmithKline's Augmentin<sup>(R)</sup> 875mg/125mg, and its anticipation of an imminent approval of the 500mg/125mg strength.

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While it is always difficult to predict pricing levels, as well as the timing of additional market entrants into this product, Teva is currently comfortable with projections of earnings per fully diluted share of \$0.88 to \$0.93 for the fourth quarter of 2002.

Today's approval follows an earlier ruling by a federal judge, which invalidated seven GlaxoSmithKline patents related to this product. GlaxoSmithKline has appealed the decision.

Mr. Israel Makov, President and CEO of Teva Pharmaceutical Industries, said: "We are currently in our launch preparations and expect to begin shipping the product shortly. This is a period of high seasonal demand for this important antibiotic, which has resulted in generic market shortages. Therefore, we look forward to the opportunity to make our generic version of Augmentin<sup>(R)</sup> available to the U. S. market."

No guidance was given for fiscal 2003.

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*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 APPROVAL OF  
500mg/125mg STRENGTH OF GENERIC VERSION OF AUGMENTIN(R)**

Jerusalem, Israel, October 30, 2002 -- Teva Pharmaceutical Industries Ltd. (Nasdaq:TEVA). Further to announcements made earlier in the day, Teva announced the receipt of U.S. Food and Drug Administration approval of its ANDA for Amoxicillin and Clavulanate Potassium Tablets, the generic version of GlaxoSmithKline's Augmentin(R) 500mg/125mg. This is the second strength of the formulation of this product for which Teva has obtained a generic drug approval.

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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: October 31, 2002