TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
December 23, 2010

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 December 2010

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 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): _____

Website: **www.tevapharm.com**

FDA Issues Complete Response Letter for Lower-Volume Glatiramer Acetate sNDA

Jerusalem, Israel, December, 23, 2010 - Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) announced today that it has received a complete response letter from the U.S. Food and Drug Administration (FDA) for its supplemental New Drug Application (sNDA) for a lower-volume (0.5mL) injection of glatiramer acetate. Copaxone&reg containing 20mg of glatiramer acetate in 1ml is the global market leader in the treatment of relapsing-remitting multiple sclerosis (RRMS).

The complete response letter stated that the FDA could not approve the application as submitted. The FDA noted that the 0.5mL formulation contained the same active ingredient as the currently marketed Copaxone&reg, but that because the mechanism of action of Copaxone&reg is not fully understood, even a formulation change could impact clinical outcomes. The Agency stated, "Unless you can provide a convincing argument that the new higher concentration/lower volume formulation does not have an impact on efficacy, an adequate and well controlled efficacy study will be needed to support efficacy of this new formulation."

This response supports Teva's belief that even slight changes to a glatiramoid like Copaxone&reg can significantly and unpredictably influence the efficacy, toxicity and immunogenicity profile of the compound. Teva intends to continue working closely with the FDA to determine the most appropriate next steps regarding the application.

The sNDA was based on the SONG trial which examined a lower-volume injection of Copaxone&reg containing 20mg of glatiramer acetate, the currently approved dose, in a 0.5mL injection. The trial was designed to explore whether a reduced-volume injection enhances the patient injection experience. The trial included nearly 150 patients in 21 centers in the U.S.

About Copaxone&reg

Copaxone&reg is indicated for the reduction of the frequency of relapses in RRMS, including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. The most common side effects of Copaxone&reg are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain. Copaxone&reg (glatiramer acetate injection) is now approved in 51 countries

worldwide, including the United States, Russia, Canada, Mexico, Australia, Israel, and all European countries. In North America, Copaxone&reg is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. In Europe, Copaxone&reg is marketed by Teva Pharmaceutical Industries Ltd. and sanofi aventis. Copaxone&reg is a registered trademark of Teva Pharmaceutical Industries Ltd.

See additional important information at

http://www.sharedsolutions.com/pdfs/PrescribingInformation.aspx or call 1-800-887-8100 for electronic releases.

About the Study

Patients (N=148) enrolled in an open-label randomized two-arm single crossover study. Half of the patients (n=76) were randomized to inject 20mg/1.0mL daily for the first 14 day period (Period 1). The other half of the patient group (n=72) injected 20mg/0.5mL daily during Period 1. During the second 14 day period (Period 2), the groups switched their injection volume formulation. The first group injected 20mg/0.5mL glatiramer acetate daily and the second group injected daily 20mg/1.0mL glatiramer acetate. Safety, tolerability, clinical and laboratory assessments occurred at the end of each period.

About Teva

Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,250 molecules and a direct presence in approximately 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, Copaxone&reg, is the number one prescribed treatment for multiple sclerosis. Teva employs more than 40,000 people around the world and reached $13.9 billion in net sales in 2009.

Teva's 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 our 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 risks relating to: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin&reg, Lotrel&reg, Protonix&reg and Yaz&reg, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone&reg (including potential generic and oral competition for Copaxone&reg), the impact of continuing

consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of ratiopharm), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

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/ Eyal Desheh

Name: Eyal Desheh
Title: Chief Financial Officer

Date December 23, 2010