TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
September 24, 2008

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 September 2008

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): 82-_____

www.tevapharm.com

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TEVA`S PROAIR&reg HFA, THE MARKET LEADING ALBUTEROL INHALER, RECEIVES NEW PEDIATRIC INDICATION

Jerusalem, Israel, September 23, 2008 -Teva Pharmaceutical Industries Ltd. today announced that the U.S. Food and Drug Administration (FDA) has approved ProAir&reg HFA (albuterol sulfate) Inhalation Aerosol for use in patients as young as 4 years of age. Previously, ProAir HFA had been indicated for use in patients aged 12 and older.

In clinical studies, ProAir HFA, the market leading albuterol sulfate inhaler,[1] exhibited significant bronchodilator efficacy in pediatric asthmatics aged 4 to 11 years. ProAir HFA provides physicians with a treatment option to help relieve children's asthma symptoms as they occur wherever they occur, [2] which is especially important as children return to school. With asthma affecting more than one child in every 20 in the United States,[3] studies show that asthma emergency room and hospitalization rates spike in September.[4]

For environmental reasons, the FDA and U.S. Environmental Protection Agency (EPA)[5] have mandated the transition from chlorofluorocarbon (CFC)-based albuterol inhalers to HFA albuterol inhalers by the end of this year. "Teva is committed to ensuring a smooth HFA transition and also to providing support for patients using ProAir HFA," said Mark Salyer, General Manager, Teva Specialty Pharmaceuticals.

Teva has been providing doctors and patients with a variety of educational and cost saving tools to help educate and increase access to ProAir. Doctors, parents and patients can access this information at www.ProAirHFA.com and www.Switch2HFA.com.

About Pediatric Asthma

Asthma is a chronic disorder characterized by inflammation of the air passages and spasm of the muscles around those air passages, both of which result in the narrowing of the airways that transport air into the lungs.[6] Asthma symptoms, such as coughing, wheezing, chest tightness and shortness of breath, can occur and can impact multiple aspects of patients' lives.[6] Asthma is the most common chronic condition among children,[7] currently affecting an estimated 6.8

million children under 18 years of age, 4.1 million of whom suffered from an asthma attack or episode in 2006.[8] Asthma is also responsible for almost 3 million physician visits and 200,000 hospitalizations among children each year in the United States.[3] It also is the third leading cause of hospitalization among children.[3]

About Teva

Teva Specialty Pharmaceuticals-USA is the U.S.-based respiratory division of Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Europe.

See additional important information at www.ProAirHFA.com or www.Switch2HFA.com. For hard copy releases, please see enclosed full prescribing information.

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ProAir&reg HFA (albuterol sulfate) Inhalation Aerosol is indicated in patients 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

Important Safety Information

If your symptoms become significantly worse when you use ProAir&reg HFA, contact your doctor immediately. This may indicate either a worsening of your asthma or a reaction to the medication, which may rarely occur with the first use of a new canister of ProAir&reg HFA. Either of these could be life-threatening.

What to tell your doctor before using ProAir&reg HFA: If you have a heart, blood, or seizure disorder, high blood pressure, diabetes, or an overactive thyroid, be sure to tell your doctor. Also make sure your doctor knows all medications you are taking - especially heart medications and drugs that treat depression - because some medications may interfere with how well your asthma medications work. Do not exceed the recommended dose.

Side effects associated with ProAir&reg HFA included headache, rapid heart beat, pain, dizziness, and irritation of the throat and nose.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

REFERENCES:

1. IMS Health National Prescription Audit. Total Rx Data. July 2008.

2. ProAir&reg HFA Package Insert, 2008.

3. "Asthma Facts and Figures." Asthma and Allergy Foundation of America, 2005. http://www.aafa.org/display.cfm?id=8&sub=42

4. Johnston, NW et al. The September Epidemic of Asthma Hospitalization: School Children as Disease Vectors. *Journal of Allergy and Clinical Immunology*. March 2006. Vol. 117(3); 557-562.

5. U.S. Food and Drug Administration. Questions and answers on final rule of albuterol MDI`s. Available at: http://www.fda.gov/cder/mdi/mdifaqs.htm. Accessed May 2008.

6. "What is Asthma?" National Heart Lung and Blood Institute, May 2006. http://www.nhlbi.nih.gov/health/dci/Diseases/Asthma/Asthma_WhatIs.html

7. "Chronic Conditions: A Challenge for the 21st Century," National Academy on an Aging Society, 2000.

8. Centers for Disease Control and Prevention: National Center for Health Statistics, National Health Interview Survey Raw Data, 2006. Analysis by the American Lung Association Research and Program Services Division using SPSS and SUDAAN software. Available at: http://www.lungusa.org/site/c.dvLUK9O0E/b.4061173/apps/s/content.asp?ct=3227479. Accessed September 16, 2008.

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, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Allegra&reg , Neurontin&reg, Lotrel&reg and Protonix&reg, the effects of competition on our innovative products, especially Copaxone&reg 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 Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to achieve expected results through our innovative R&D efforts, our ability to successfully identify, consummate and integrate acquisitions, including the pending acquisition of Barr Pharmaceuticals Inc., potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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: September 23, 2008