DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-457/S-013

Teva Global Respiratory Research, LLC
4400 Biscayne Blvd.
Miami, FL 33137

Attention: Axel G. Perlwitz, Ph.D.
Associate Director, Regulatory Affairs

Dear Dr. Perlwitz:

Please refer to your supplemental new drug application dated November 15, 2007 received November 16, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proair HFA (albuterol sulfate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated March 28, May 2, and 9, June 27, July 29, August 12, September 8, and 12, 2008.

This supplemental new drug application provides for the use of Proair HFA (albuterol sulfate) Inhalation Aerosol for the treatment or prevention of bronchospasm with reversible obstructive airway disease in patients 4 through 11 years, and for the prevention of exercise-induced bronchospasm (EIB) in patients 4 through 11 years.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We remind you of your agreement to submit an application for implementation of the MDI Dose Counter for Proair HFA Inhalation Aerosol.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, Patient Instruction for Use) and submitted on September 12, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 21-457/S-013”.

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Pulmonary and Allergy Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Akilah Green, Regulatory Project Manager, at (301) 796-1219.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (Pkg insert, Patient's Instructions for Use)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury

9/16/2008 10:41:10 AM