NDA 21-457/S-022

SUPPLEMENT APPROVAL

Teva Branded Pharmaceutical Products R&D, Inc.
74 NW 176th Street
Miami, Florida 33169

Attention: Axel Perlwitz
Associate Director, Regulatory Affairs

Dear Mr Perlwitz:

Please refer to your Supplemental New Drug Application (sNDA) dated June 7, 2010, received June 7, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ProAir (albuterol sulfate) Inhalation Aerosol.

We acknowledge receipt of your amendments dated, December 8 and 1, 2010.

This "Prior Approval" supplemental new drug application provides for proposed artwork changes for the carton and container labels.

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

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on December 8, 2010, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 21-457/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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 Angela Ramsey, Regulatory Project Manager, at (301) 796-2284.

Sincerely,

{See appended electronic signature page}

Lydia Gilbert-McClain, M.D., FCCP
Deputy Division Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

ANGELA H ROBINSON
12/08/2010

LYDIA I GILBERT MCCLAIN
12/08/2010