DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202813/S-006

**SUPPLEMENT APPROVAL**

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

Attention: William Kiddell
Associate Director, Regulatory Affairs

Dear Mr. Kiddell:

Please refer to your Supplemental New Drug Application (sNDA) dated January 10, 2014, received January 13, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) Qnasl (beclomethasone dipropionate) Nasal Aerosol, 80 mcg.

We acknowledge receipt of your amendments dated June 19 and July 2, 2014.

This Changes Being Effected supplemental new drug application proposes to modify the labeling such that the canister is packaged within the carton with the valve in the upright orientation.

## APPROVAL & LABELING

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 carton/container labeling.

## CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, 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 *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 "**Final Printed Carton and Container Labels for approved NDA 202813/S-006**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

**REPORTING REQUIREMENTS**

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 Carol F. Hill, Safety Regulatory Project Manager, at (301) 796-1226.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE:
Carton and Container Labeling

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

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/s/

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CAROL F HILL
07/10/2014

BADRUL A CHOWDHURY
07/10/2014