DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202813/S-007 & S-009

SUPPLEMENT APPROVAL AND
POSTMARKETING REQUIREMENT FULFILLED

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

Attention: Jacqueline Howard
Manager, Regulatory Affairs, Respiratory Therapeutic Area

Dear Ms. Howard:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 27 and December 4, 2014, received February 27 and December 4, 2014, for supplements 007 and 009, respectively, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Qnasl (beclomethasone dipropionate) Nasal Aerosol, 40 mcg.

We acknowledge receipt of your amendments dated April 15 and 21, May 28, June 2, September 8, October 24, November 26, and December 3, 4 and 12, 2014.

These prior approval supplemental new drug applications, S-007 and S-009 propose indications for the treatment of the nasal symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis, respectively in patients 4 through 11 years of age.

APPROVAL & LABELING

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

EXPIRATION DATING PERIOD

For the Qnasl (beclomethasone dipropionate) Nasal Aerosol, 40 mcg, 60 actuation presentation, 18-months expiry dating has been granted and 12-months expiry dating has been granted for the 120 actuation presentation.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, text for the patient package insert, and text for the instructions for use, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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-007 and S-009**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We refer you to the Agency letter dated December 5, 2012, where we waived the pediatric study requirement for ages less than 4 years because we agreed that the current nasal actuator is too large to fit in the nostrils of typical pediatric subjects less than 4 years of age. In addition, we have local and ocular safety concerns in young children as a consequence of the inability to provide accurate dose delivery using the current nasal actuator in pediatric patients less than 4 years of age. We also note that attempts to modify the nasal actuator to make it smaller resulted in a change in the drug delivery characteristics.

Therefore, we waived the pediatric study requirement for ages less than 4 years for the reasons stated above and because you have demonstrated that reasonable attempts to produce a pediatric formulation necessary for this age group have failed. As required by section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act, the documentation you have provided that details why a pediatric formulation cannot be developed will be posted on the Agency's public website.

Your February 27, 2014, submission contained the final reports for the following postmarketing requirement listed in the March 23, 2012, approval letter and the subsequent Acknowledge New Postmarketing Requirement letter dated December 5, 2012.

#1882-1	Conduct a 2-week double-blind, placebo-controlled dose-ranging trial in children 6-11 years of age with seasonal allergic rhinitis. At least 2 doses of Qnasl will be evaluated.
#1976-1	Conduct a 12-week double-blind, placebo controlled safety and efficacy trial in children 4-11 years of age with perennial allergic rhinitis.

We have reviewed the final reports and conclude that the above requirements were fulfilled. This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our March 23 and December 5, 2012 correspondences.

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}

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

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

/s/

LYDIA I GILBERT MCCLAIN
12/17/2014