DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202813

NDA APPROVAL

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

Attention: William Kiddell
Senior Manager, Regulatory Affairs, GRR&D

Dear Mr. Kiddell:

Please refer to your New Drug Application (NDA) dated May 24, 2011, received May 24, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Qnasl (beclomethasone dipropionate) Nasal Aerosol 80 mcg.

We acknowledge receipt of your amendments dated May 27, August 2, 4, and 24, September 15 21, 27, and 29, October 6, and 27 and December 13, 2011, and February 8 and 29, March 8, 9, 19, 20, and 21, 2012.

This new drug application provides for the use of Qnasl (beclomethasone dipropionate) Nasal Aerosol 80 mcg for the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older.

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

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, the patient package insert, and the patient instructions for use. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels submitted on March 21, 2012, 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 "**Final Printed Carton and Container Labels for approved NDA 202813**." 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 are waiving the pediatric study requirement for ages 0 to 2 years because the product would be unsafe in this pediatric group. This is because there are concerns of local and systemic toxicity with corticosteroids and other treatments are available for allergic rhinitis.

We are deferring submission of your pediatric study for ages 2 to 11 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

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.

The timetable you submitted on March 19, 2012, states that you will conduct this trial according to the follow schedule:

Final Report Submission: December 2013

1882-2 Conduct a 12-week double-blind, placebo controlled safety and efficacy trial in children 6-11 years of age with perennial allergic rhinitis.

The timetable you submitted on March 19, 2012, states that you will conduct this trial according to the following schedule:

Final Protocol Submission: September 2012
Trial Completion: September 2013
Final Report Submission: December 2013

1882-3 Conduct a 6-week, double-blind, placebo-controlled trial to assess the effects of QNASL on the HPA axis in children 6-11 years of age with perennial allergic rhinitis

The timetable you submitted on March 19, 2012, states that you will conduct this trial according to the following schedule:

Final Protocol Submission: October 2012
Trial Completion: July 2013
Final Report Submission: December 2013

1882-4 Conduct a 12-week double-blind, placebo-controlled safety trial in children 2-5 years of age with perennial allergic rhinitis.

The timetable you submitted on March 19, 2012, states that you will conduct this trial according to the following schedule:

Final Protocol Submission: October 2012
Trial Completion: October 2013
Final Report Submission: December 2013

1882-5 Conduct a 6-week double-blind, placebo-controlled trial to assess the effects

of QNASL on the HPA axis in children 2-5 years of age with perennial allergic rhinitis.

The timetable you submitted on March 19, 2012, states that you will conduct this trial according to the following schedule:

Final Protocol Submission:	November 2012
Trial Completion:	August 2013
Final Report Submission:	December 2013

Submit the protocols to your IND 101639, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

This product is appropriately labeled for use in ages 12 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, Senior Regulatory Health 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 Research and Evaluation

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/

BADRUL A CHOWDHURY
03/23/2012