DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21861/S-009

SUPPLEMENT APPROVAL

Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134-2099

Attention: Randy Russell
Associate Director, Regulatory Affairs

Dear Mr. Russell:

Please refer to your Supplemental New Drug Application (sNDA) dated August 25, 2011, received August 26, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Patanase® (olopatadine hydrochloride) Nasal Spray.

We acknowledge receipt of your amendments dated December 5, 2011, and January 10, and February 8, 9, and 21, 2012.

This Prior Approval supplemental new drug application provides for revisions to the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS-Clinical Trial Experience sections of the package insert to reflect the results of the Post Marketing Trial "Safety of Patanase®" Nasal Spray in Patients with Perennial Allergic Rhinitis" (C-08-32), and the addition of information regarding anosmia and hyposmia ADVERSE REACTIONS-Post Marketing Experience section of the package insert.

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.

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, 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 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).

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 Miranda Raggio, Senior Regulatory Project Manager, at (301) 796-2109.

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/Office of New Drugs
Center for Drug Evaluation and Research

Content of Labeling: US Prescribing Information (Package Insert) submitted February 21, 2012

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
02/22/2012
Deputy Director