DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20468/S-033
NDA 20468/S-034

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING
COMMITMENTS

Sanofi-Aventis U.S., LLC
US 55 Corporate Drive
Bridgewater, New Jersey 08807

Attention: Payal Patel, Pharm.D.
Manager, General Therapeutics
US Regulatory Affairs Marketed Products

Dear Dr. Patel:

Please refer to your Supplemental New Drug Applications (sNDA) dated November 21, 2012, received November 27, and 28, 2012, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasacort AQ (triamcinolone acetonide) Nasal Spray.

We acknowledge receipt of your amendments dated January 8, 11, 18, February 15, April 22, June 17, June 24, and June 27, 2013.

Prior approval supplemental new drug application NDA 20-468/S-033 proposes to revise the labeling for Nasacort AQ Nasal Spray to include information from a postmarketing growth study.

Prior approval supplemental new drug application NDA 20-468/S-034, proposes to revise the labeling for Nasacort AQ Nasal Spray to include information from a postmarketing HPA axis study.

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.

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 Information Leaflet), 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).

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.

Because none of these criteria apply to your applications, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING COMMITMENTS

We have received your submission dated April 13, 2011, containing the final report for the following postmarketing commitment listed in the September 19, 2008, approval letter.

232-1 A controlled clinical trial in pediatric patients with perennial allergic rhinitis to assess the effect of Nasacort AQ (triamcinolone acetonide) Nasal Spray on the HPA axis. Submit a labeling supplement reflecting the results of the clinical trial.

We have also received your submission dated June 22, 2012, containing the final report for the postmarketing commitment to conduct a one year growth study in pediatric patients with Nasacort AQ Nasal Spray.

We have reviewed your submissions and conclude that the above commitments were fulfilled.

This completes all of your postmarketing commitments acknowledged in our September 19, 2008, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on 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 Wayne Amchin, Senior Regulatory Health Project Manager for Safety, at (301) 796-0421.

Sincerely,

{See appended electronic signature page}

Sally M. Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

SALLY M SEYMOUR
07/02/2013