DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020468/S-035

SUPPLEMENT APPROVAL

sanofi-aventis U.S., LLC
Attention: Judith R. Plon, M.B.A., R.A.C.
Associate Vice President, Global Regulatory Affairs
55 Corporate Drive, Mail Stop: 55D-220B
Bridgewater, NJ 08807

Dear Ms. Plon:

Please refer to your Supplemental New Drug Application (sNDA) dated December 13, 2012, received December 13, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasacort Allergy 24 HR (triamcinolone acetonide) nasal spray, 55 mcg per spray.

We acknowledge receipt of your amendments dated December 14, 2012, February 7, March 22, April 9, 10, and 11, June 4, 13, and 21, July 18, August 6, 15, 16, and 23, September 13 and 26, and October 2, 7, and 10, 2013.

This "Prior Approval" supplemental new drug application provides for the over-the-counter use of Nasacort Allergy 24 HR for the temporary relief of symptoms of hay fever or other respiratory allergies (nasal congestion, runny nose, sneezing, and itchy nose) in adults and children ages 2 years 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 agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labels as listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Labels submitted on October 2, 2013:

- bottle cap labels

Labels submitted on October 10, 2013:

- 30, 60, 120-count carton and immediate container (bottle)
- 30, 60, 120-count carton with coupons
- 30, 60, 120-count clamshell

- bulk packaging (2 x 120, 3 x 120, and 4 x 120)
- consumer package insert labels

The FPL should be submitted 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 Labeling for approved NDA 020468/S-035**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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. In addition, representative container or carton labeling, whichever includes Drug Facts (where differences exist only in the quantity of contents statement), should be submitted as a JPG file.

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 application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

2086-1: Perform a leachable study of the container closure labeling for each fill weight (6.5 g, 10.5 g, and 16.5 g) for 24 months at 25°C/60% RH.

The timetable you submitted on October 7, 2013, states that you will conduct this study according to the following schedule:

Final Report Submission: February 29, 2016

Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected study completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

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 questions, call Jeffrey Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

RADM (Retired) Sandra Kweder, M.D., F.A.C.P.
Director (acting)
Office of Drug Evaluation IV
Office of New Drugs
Center for Drug Evaluation and Research

and

{See appended electronic signature page}

Curtis J. Rosebraugh, M.D., M.P.H.
Director
Office of Drug Evaluation II
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:
Consumer Package Insert, Carton and Immediate 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.

/s/

SANDRA L KWEDER
10/11/2013

CURTIS J ROSEBRAUGH
10/11/2013