



NDA 020468/S-039

SUPPLEMENT APPROVAL

Sanofi Aventis US LCC
Attention: Payal Patel, Pharm.D.
Manager, US Regulatory Affairs Marketed Products
55 Corporate Drive, Mailstop: 55C-205A
Bridgewater, NJ 08807

Dear Dr. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated March 21, 2014, received March 21, 2014 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nasacort® Allergy 24HR (triamcinolone acetonide) nasal spray, 55 mcg per spray.

This sNDA proposes updates to the bottle booklet label incorporating the two additional printing colors approved in S-038.

We have completed our review of this application. 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 60- and 120-spray bottle booklet labels submitted on March 21, 2014, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

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-039.**” 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.

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 Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:

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/

THERESA M MICHELE
09/19/2014