



NDA 020746/S-037

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
Authorized Agent for McNeil Consumer Healthcare Division
Attention: Jennifer Norman, R.Ph.
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2210

Dear Ms. Norman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 22, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rhinocort® Allergy Spray (budesonide nasal spray), 32 mcg per spray.

This “Prior Approval” supplemental new drug application provides for new labeling in the form of tertiary packaging for Rhinocort® Allergy Spray, 60 and 120 sprays.

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the labeling listed in Table 1 below, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Table 1: Final Printed Labeling Requested

Submitted Labeling	Submission Date
60-count outer container (clamshell)	03/13/2017
120-count outer container (clamshell)	03/13/2017
60-count outer container (carton)	05/17/2017
120-count outer container (carton)	05/17/2017
60-count immediate container (bottle)	05/17/2017

120-count immediate container (bottle)	05/17/2017
package insert	05/17/2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 020746/S-037.**” 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.

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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
05/22/2017