



NDA 20021/S-012

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division
Attention: Jennifer Norman, RPh
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Norman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 11, 2018, and associated amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sudafed Sinus Congestion 24 Hour (pseudoephedrine hydrochloride) extended-release tablet, 240 mg.

This “Prior Approval” supplemental new drug application provides for a change in the proprietary name and associated labeling changes. 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 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

Labeling Item	Submission Date
10-count outer container (carton)	11/02/2018
5-count immediate container (blister)	11/02/2018

The FPL 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 (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20021/S-12.**” 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 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
11/13/2018