



NDA 021585/S-025

**SUPPLEMENT APPROVAL**

Reckitt Benckiser, Inc.  
Attention: Douglas Flint  
Manager, Regulatory Affairs  
399 Interpace Parkway  
Parsippany, NJ 07054

Dear Mr. Flint:

Please refer to your Supplemental New Drug Application (sNDA) dated August 23, 2010, received August 24, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Maximum Strength Mucinex<sup>®</sup> D (guaifenesin and pseudoephedrine hydrochloride) extended-release tablets, 1200mg/120mg.

This “Prior Approval” supplemental new drug application provides for the addition of a new container closure system for an immediate container (foil pouch) containing one tablet, and the associated labeling revisions.

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (1-count immediate container (pouch) and 24-count carton labels submitted on August 23, 2010), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The final printed labeling 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 021585/S-025.**” 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.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

## **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}*

Joel Schiffenbauer, M.D.  
Deputy Director  
Division of Nonprescription Clinical Evaluation  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Enclosures:

Carton and Immediate 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/  
-----

JOEL SCHIFFENBAUER  
12/20/2010