



NDA 21282-S037, 21585-S026 & 21620-S031

APPROVAL LETTER

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

Dear Mr. Flint:

Please refer to your three Supplemental New Drug Applications (sNDA) dated November 10, 2010 and received on November 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the products listed in the following table.

NDA#	Supplement#	Product Description
21-282	037	Mucinex [®] (guaifenesin) Tablets, Extended Release
21-585	026	Mucinex [®] D (guaifenesin and Pseudoephedrine HCl) Tablets, Extended Release
21-620	031	Mucinex [®] DM (guaifenesin and dextromethorphan HBr) Tablets, Extended Release

These supplemental applications, submitted as “Changes Being Effected in 30 days,” provides for direct debossing of lot number and expiration date on the multiple-tablet blister cards for the drug products.

We have completed our review of these supplemental new drug applications. These supplements are approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch IX, Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

JAMES D VIDRA
05/12/2011