DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-282/S-035 and 21-620/S-029

APPROVAL LETTER

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

Dear Mr. Flint:

Please refer to your four Supplemental New Drug Applications (sNDA) submitted September 20, 2010 and received September 21, 2010 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	035	Mucinex® (guaifenesin) Extended Release Bi-Layer Tablets
21-620	029	Mucinex® DM (guaifenesin and dextromethorphan HBr) Extended Release Bi-Layer Tablets

These "Changes Being Effected in 30 days" supplemental new drug applications provide for an alternate pouch packaging site (b) (4).

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
03/11/2011