



NDA 21282/S-043 and 21585/S-030

**APPROVAL LETTER**

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

Dear Mr. Flint:

Please refer to your Supplemental New Drug Applications (sNDA) dated November 22, 2013, received November 25 and 26, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 21282	S-043	Mucinex® (guaifenesin) Extended Release Tablets
NDA 21585	S-030	Mucinex® D (guaifenesin/pseudoephedrine HCl) Extended Release Tablets

These “Changes Being Effected in 30 days” supplemental new drug applications provide for addition of an alternate stability testing site 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 Rebecca McKnight, Regulatory Project Manager, at (301) 796-1765.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, 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/  
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RAMESH RAGHAVACHARI  
05/22/2014