



NDA 21282/S-044

**APPROVAL LETTER**

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

Dear Mr. Flint:

Please refer to your Supplemental New Drug Application (sNDA) dated March 4, 2014, received March 5, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex® ER (guaifenesin and dextromethorphan HBr) Tablets.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the addition of an alternate packaging site, Reckitt Benckiser Healthcare International Ltd., in Nottingham, United Kingdom.

We have completed our review of this supplemental new drug application. This supplement is 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  
09/10/2014