



NDA 21282/S-045

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 November 5, 2014, received November 6, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex® (guaifenesin) Extended-Release Tablets.

This “Prior Approval” supplemental new drug application provides for the revision of release and stability specification for drug product.

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,

Ramesh
Raghavachari -S

Digitally signed by Ramesh Raghavachari S
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ou=FDA, ou=People
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