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.

<table>
<thead>
<tr>
<th>NDA#</th>
<th>Supplement#</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-282</td>
<td>035</td>
<td>Mucinex® (guaifenesin) Extended Release Bi-Layer Tablets</td>
</tr>
<tr>
<td>21-620</td>
<td>029</td>
<td>Mucinex® DM (guaifenesin and dextromethorphan HBr) Extended Release Bi-Layer Tablets</td>
</tr>
</tbody>
</table>

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.

Reference ID: 2917011
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
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES D VIDRA
03/11/2011

Reference ID: 2917011