Dear Ms. Firor:

Please refer to your supplemental new drug applications dated and received September 3, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following.

<table>
<thead>
<tr>
<th>Drug</th>
<th>NDA  #</th>
<th>Supplement #</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEXIUM (esomeprazole magnesium) For Delayed-Release Oral Suspension</td>
<td>22-101</td>
<td>004</td>
</tr>
<tr>
<td>NEXIUM (esomeprazole magnesium) Delayed-Release Capsules</td>
<td>21-153</td>
<td>034</td>
</tr>
<tr>
<td>NEXIUM (esomeprazole magnesium) For Delayed-Release Oral Suspension</td>
<td>21-957</td>
<td>007</td>
</tr>
<tr>
<td>NEXIUM (esomeprazole sodium) For Injection</td>
<td>21-689</td>
<td>015</td>
</tr>
</tbody>
</table>

We acknowledge receipt of your submissions for the above NDAs dated November 10, 2009, and January 6, 2010. We also acknowledge receipt of your submission dated September 22, 2009, for NDA 21-153.

These "Prior Approval” supplemental new drug applications provide for the following changes to the package inserts (PIs):

- Drug Interactions section: add information regarding the drug-drug interaction of omeprazole (a CYP 2C19 inhibitor) and cilostazole (metabolized by CYP 2C19)
- Clinical Pharmacology section: add information regarding Clostridium difficile infections in hospitalized patients taking omeprazole
- Other administrative revisions

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CONTENT OF LABELING**
As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at [http://www.fda.gov/oc/datacouncil/spl.html](http://www.fda.gov/oc/datacouncil/spl.html) that is identical to the enclosed labeling. For administrative purposes, please designate this submission, “SPL for approved NDA 21-101/S-004, 21-153/S-034, 21-957/S-007, 21-689/S-015”.

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package inserts to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package inserts, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see [http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm).

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).
If you have any questions, call Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D.
Deputy Director, Safety
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures: Package Inserts (oral and IV)
<table>
<thead>
<tr>
<th>Application Type/Number</th>
<th>Submission Type/Number</th>
<th>Submitter Name</th>
<th>Product Name</th>
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</thead>
<tbody>
<tr>
<td>NDA-22101</td>
<td>SUPPL-4</td>
<td>ASTRazeneca LP</td>
<td>NEXIUM</td>
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<tr>
<td>NDA-21957</td>
<td>SUPPL-7</td>
<td>ASTRazeneca LP</td>
<td>NEXIUM DELAYED-RELEASE GRANULES FOR ORAL</td>
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<td>NDA-21689</td>
<td>SUPPL-15</td>
<td>ASTRazeneca LP</td>
<td>NEXIUM IV</td>
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<tr>
<td>NDA-21153</td>
<td>SUPPL-34</td>
<td>ASTRazeneca LP</td>
<td>NEXIUM 20/40MG DELAYED RELEASE CAPSULES</td>
</tr>
</tbody>
</table>

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

/s/

JOYCE A KORVICK
03/04/2010