Dear Dr. Valas:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arimidex® (anastrozole) Tablets.

<table>
<thead>
<tr>
<th>SLR</th>
<th>Letter date</th>
<th>Received date</th>
<th>Regulatory due date</th>
<th>Provides for</th>
<th>Type</th>
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<tbody>
<tr>
<td>SLR-020</td>
<td>February 23, 2007</td>
<td>February 23, 2007</td>
<td>August 23, 2007</td>
<td>Adverse Events (clarifying ischemic cardiovascular events and adding carpal tunnel events)</td>
<td>Changed Being Effected</td>
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<tr>
<td>SLR-023</td>
<td>November 29, 2007</td>
<td>November 29, 2007</td>
<td>May 29, 2008</td>
<td>Conversion to PLR</td>
<td>Prior Approval</td>
</tr>
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</table>

We acknowledge receipt of your November 4, 2008 submission to SLR-023.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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)] 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 (text for the package insert, text for patient package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 20,541/SLR-020/SLR-021/SLR-023.”

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:
MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Alice Kacuba, Chief, project Management Staff at (301) 796-1381.

Sincerely,

{See appended electronic signature page}

Robert Justice. M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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

/s/

Robert Justice
12/10/2008 06:18:20 PM