



NDA 19810/S-092  
NDA 22056/S-008

**SUPPLEMENT APPROVAL**

AstraZeneca LP  
Attention: Judy Firor  
Director, Regulatory Affairs  
1800 Concord Pike, P.O. Box 8355  
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your Supplemental New Drug Application (sNDA) dated September 2, 2010, received September 2, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec (omeprazole) Delayed-Release Capsules and Prilosec (omeprazole magnesium) For Delayed Release Oral Suspension.

We acknowledge receipt of your submissions, dated September 2, September 17, October 28, and November 29, December 8 and 13, 2010, and January 19, 2011.

This supplemental new drug application provides for revisions to the labeling for Prilosec (omeprazole) Delayed-Release Capsules and Prilosec (omeprazole magnesium) For Delayed-Release Oral Suspension to reflect changes to the package insert describing the interaction between omeprazole and Plavix (clopidogrel), consistent with our email correspondences, last of which is dated January 17, 2011.

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

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to, the enclosed labeling, including labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the

guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions approved in this supplemental application.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

If you have any questions, call Frances Fahnbulleh, Regulatory Project Manager, at (301) 796-0942.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):  
Content of Labeling

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

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JOYCE A KORVICK  
01/20/2011