DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-888/S-045

AstraZeneca Pharmaceuticals LP
Attention: Paula R. Clark
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

SUPPLEMENT APPROVAL

Dear Ms. Clark:

Please refer to your supplemental new drug application (NDA) dated November 20, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zestoretic (lisinopril and hydrochlorothiazide) Tablets.

This changes being effected supplemental new drug application provides for the following revisions to the labeling:

1. Under **ADVERSE REACTIONS** section, subsection **Angioedema**, removal of the word "rarely".
2. Under **ADVERSE REACTIONS**, subsection **Nervous System/Psychiatric**, the following text was added to the end of this subsection, "…mood alterations (including depressive symptoms)."

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the electronic draft labeling text. Submit 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, that is identical in content to the submitted electronic labeling dated November 20, 2008. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, please call Michael Monteleone, M.S., Regulatory Project Manager, at (301)796-1952.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

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

/s/

Norman Stockbridge

5/20/2009 04:05:18 PM