



NDA 18-343/S-081

Par Pharmaceutical, Inc.
Attention: Ms. Mona Desai
One Ram Ridge Road
Spring Valley, NY 10977

Dear Ms. Desai:

Please refer to your supplemental new drug application dated May 7, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Capoten (captopril) 12.5, 25, 50 and 100 mg Tablets.

This Changes Being Effected supplemental application provides for additional information in the **PRECAUTIONS/Drug Interactions** section of the package insert as requested in our letter dated March 3, 3008.

This supplemental new drug application provides for electronic draft labeling with the following revision:

Gold: Nitritoid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including CAPOTEN.

We also note the last revised labeling date and version number has been updated to March 2008 and OS793-01-1-02, respectively.

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 SPL.

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

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:

Alisea Crowley, Pharm.D.
Senior Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

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

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/s/

Norman Stockbridge
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