DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-885/S-019

Pfizer Inc.
Attention: Mr. James A. Parker, Jr.
235 East 42nd Street
New York, NY 10017

Dear Mr. Parker:

Please refer to your supplemental new drug application dated July 5, 2000, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Accupril (quinapril hydrochloride) 5, 10, 20 and 40 mg Tablets.

We acknowledge receipt of your submission dated January 24, 2002, that constitutes a complete response to our approvable letter dated July 19, 2001.

This supplemental new drug application provides for Final Printed Labeling revised as follows:

1. An addition to the end of the **PRECAUTIONS/Drug Interaction/Other Agents** subsection:

   Co-administration of multiple 10 mg doses of atorvastatin with 80 mg of ACCUPRIL resulted in no significant change in the steady-state pharmacokinetic parameters of atorvastatin.

2. The first two paragraphs of the **ADVERSE REACTIONS/Overdosage** subsection have been revised from:

   No data are available with respect to overdosage in humans. Doses of 1440 to 4280 mg/kg of quinapril cause significant lethality in mice and rats.

   The most likely clinical manifestation would be symptoms attributable to symptoms attributable to severe hypotension.

   to:

   Doses of 1440 to 4280 mg/kg of quinapril cause significant lethality in mice and rats.

   No specific information is available on the treatment of overdosage with quinapril. The most likely clinical manifestation would be symptoms attributable to severe hypotension.

We completed our review of this supplemental new drug application for use as recommended in the final printed labeling package insert included in your January 24, 2002 submission. According, this supplemental new drug application is approved effective on the date of this letter.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5309

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Doug Throckmorton
7/22/02 10:56:37 AM