DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-885/S-023
NDA 20-125/S-003

Pfizer Inc.
Attention Ms. Rita A.Wittich
235 East 42nd Street
New York, NY 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug applications dated June 6, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accupril (quinapril hydrochloride) 5, 10, 20 and 40 mg Tablets (NDA 19-885) and Accuretic (quinapril hydrochloride/hydrochlorothiazide) 10/12.5, 20/12.5 and 20/25 mg Tablets (NDA 20-125).

We acknowledge receipt of your submissions dated June 9, 2003.

These "Changes Being Effected" supplemental new drug applications provide for changes to the **WARNINGS** section of labeling as follows:

1. Under **WARNINGS,** the **Angioedema** subsection was re-titled "**Head and Neck Angioedema**".

2. Following the **Head and Neck Angioedema** subsection and before the paragraph entitled "In large U.S. postmarketing study…" the following text has been added:

   Intestinal Angioedema: Intestinal angioedema has been reported in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. The angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor. Intestinal angioedema should be included in the differential diagnosis of patients on ACE inhibitors presenting with abdominal pain.

In addition, we note the following revisions:

NDA 19-885/S-023

- Under the **ADVERSE REACTIONS/**Hypertension and/or Heart Failure subsection, the following additions have been made to the General and Gastrointestional subsections, respectively:
  Anaphylactoid reaction, dyspepsia

- Under the **HOW SUPPLIED** section, the manufacturer has been changed
  from: Parke Davis

  to: Pfizer Pharmaceuticals, Ltd.

NDA 20-125/S-003

- Under the **ADVERSE REACTIONS/**Postmarketing Experiences subsection, the following addition has been made to the BODY AS A WHOLE subsection:
  Anaphylactoid reaction

- Under the **HOW SUPPLIED** section, the following changes have been made:

  from: **10/12.5 tablets:** pink, scored elliptical, biconvex, film-coated tablets. Each tablet contains 10 mg of quinapril and 12.5 mg of hydocholorothiazide.
  N0071-0222-06: 30 tablets (3 blisters - 10 tablets each)

  to: **10/12.5 tablets:** pink, scored elliptical, biconvex, film-coated tablets coded "PD 222" on one side. Each tablet contains 10 mg of quinapril and 12.5 mg of hydrochlorothiazide.
  N0071-0222-23: 90 tablet bottles

  from: **20/12.5 tablets:** pink, scored triangular, film-coated tablets. Each tablet contains 20 mg of quinapril and 12.5 mg of hydrochlorothiazide.
  N0071-0220-06: 30 tablets (3 blisters -10 tablets each

  to: **20/12.5 tablets:** pink, scored triangular, film-coated tablets coded "PD 220" on one side. Each tablet contains 20 mg of quinapril and 12.5 mg of hydrochlorothiazide.
  N0071-0220-23: 90 tablet bottles

  from: **20/25 tablets:** pink, scored round, biconvex, film-coated tablets. Each tablet contains 20 mg of quinapril and 25 mg of hydrochlorothiazide.
  N00071-0223-06: 30 tablets (3 blisters -10 tablets each)

  to: **20/25 tablets:** pink, round, biconvex, film-coated tablets coded "PD 223" on one side. Each tablet contains 20 mg quinapril and 25 mg of hydrochlorothiazide.
  N0071-0223-23: 90 tablet bottles

  from: Dispense in well-closed containers as defined in the USP.

  to: Dispense in tight containers as defined in the USP.

  from: Parke Davis

  to: Pfizer Pharmaceuticals, Ltd.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) dated June 6, 2003.

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, HFD-410
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 contact:

Alisea Sermon, Pharm.D.
Regulatory Project Manager
(301) 594-5334

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

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