DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-885/S-028

Pfizer Inc.
Attention: Kathleen Collins
Manager, Worldwide Regulatory Strategy
235 East 42nd Street (685/18/62)
New York, NY 10017

SUPPLEMENT APPROVAL

Dear Ms. Collins:

Please refer to your supplemental new drug application (NDA) dated April 24, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accupril (quinapril hydrochloride) tablets.

This changes being effected supplemental new drug application provides for the following addition under the **PRECAUTIONS, Drug Interactions** section of the package insert:

> **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.

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.

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}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19885	SUPPL-28	PFIZER PHARMACEUTICALS LTD	ACCUPRIL (QUINAPRIL HCL) TABLETS

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

/s/

MARY R SOUTHWORTH
09/18/2009