DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-552/S-005

Pfizer Global Pharmaceuticals
Attention: Kathy Collins-Novikov
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Collins:

Please refer to your supplemental new drug application dated May 8, 2009, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Covera-HS (verapamil hydrochloride) Extended Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for an update to the **PRECAUTIONS/Drug-Drug Interactions** section of the labeling.

The following changes have been made:

1. In **PRECAUTIONS/Drug-Drug Interactions/Other agents**, the following has been added:

   Telithromycin: Hypotension and bradyarrhythmias have been observed in patients receiving concurrent telithromycin, an antibiotic in the ketolide class.

2. Minor editorial changes have been made throughout.

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 labeling (SPL) submitted on May 8, 2009.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager
(301) 796 3975

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

Enclosure: Approved Labeling

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

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