DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18-817/S-021 **APPROVAL LETTER**

Pfizer Global Pharmaceuticals
c/o G. D. Searle, LLC
Attention: Kathleen Collins
Manager, 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, received May 8, 2009, submitted under section 505(b)(l) of the Federal Food, Drug, and Cosmetic Act for Calan (verapamil hydrochloride) Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS/Drug interactions** section of the label. The following changes have been made:

1. In **PRECAUTIONS/Drug interactions,** the section titled "**Other**" has been changed to "**Other agents**."

2. In **PRECAUTIONS/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.

3. Additional minor editorial changes have been made throughout the label.

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 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}*

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

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/
---
Mary Southworth
7/9/2009 03:30:46 PM