DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19684/S-023

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Michelle Burtness
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Burtness:

Please refer to your supplemental new drug application (sNDA) submitted March 4, 2010 under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Procardia XL (nifedipine) Extended Release Tablets.

We also acknowledge your submission dated September 1, 2010.

This Prior Approval supplemental new drug application provides for the following revisions to the **WARNINGS**, **PRECAUTIONS** and **ADVERSE EXPERIENCES** sections of the package insert:

1. There were several minor editorial revisions throughout the label. Of note, the term "GI" was replaced with the word "gastrointestinal."

2. Under the **WARNINGS, Congestive Heart Failure** section, the last sentence was changed from:

   "Patients with tight aortic stenosis may be at greater risk for such an event, as the unloading effect of nifedipine would be expected to be of less benefit to those patients, owing to their fixed impedance to flow across the aortic valve."

To reads as follows:

   "Patients with tight aortic stenosis may be at greater risk for such an event, as the unloading effect of nifedipine would be expected to be of less benefit, owing to the fixed impedance to flow across the aortic valve in these patients."

3. A new subsection was added under the **WARNINGS** section**.** It reads as follows:

Gastrointestinal Obstruction Requiring Surgery
There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of Procardia. Bezoars can occur in very rare cases and may require surgical intervention.

Cases of serious gastrointestinal obstruction have been identified in patients with no known gastrointestinal disease, including the need for hospitalization and surgical intervention.

Risk factors for gastrointestinal obstruction identified from post-marketing reports of Procardia XL (GITS tablet formulation) include alteration in gastrointestinal anatomy (severe gastrointestinal narrowing, colon cancer, small bowel obstruction, bowel resection, gastric bypass, vertical banded gastroplasty, and colostomy), hypomotility disorders (constipation, gastroesophageal reflux disease, ileus, obesity, hypothyroidism, and diabetes) and concomitant medications (H2-histamine blockers, nonsteroidal anti-inflammatory drugs, laxatives, anticholinergic agents, and levothyroxine).

4. Under **PRECAUTIONS**, the following was deleted:

   Other
   As with any other non-deformable material, caution should be used when administering Procardia XL in patients with pre-existing severe gastrointestinal narrowing (pathologic or iatrogenic). There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of Prcardia XL.

5. Under **ADVERSE EXPERIENCES**, the following new paragraph was added:

   "Gastrointestinal obstruction resulting in hospitalization and surgery, including the need for bezoar removal, has occurred in association with Procardia XL, even in patients with no prior history of gastrointestinal disease."

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

As required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (*i.e.*, a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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:

Ms. Lori 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: Content of 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 R SOUTHWORTH
10/04/2010