DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-998/S-023

G.D. Searle LLC
c/o Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: Briton Shell, Ph.D.
Director, Worldwide Regulatory Strategy

Dear Dr. Shell:

Please refer to your supplemental new drug application dated May 1, 2007, received May 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CELEBREX® (celecoxib) capsules.

We also acknowledge receipt of your submission dated June 28, 2007.

Reference is also made to the November 1, 2007, teleconference discussing revisions to the **ADVERSE REACTIONS** section of the package insert.

This Changes Being Effected (CBE-30) labeling supplement provides to the following sections of the Package Insert.

1. **ADVERSE REACTIONS**
2. **WARNINGS-Renal Effects**
3. **PRECAUTIONS-General**
4. **PRECAUTIONS-DRUG INTERACTIONS-ACE Inhibitors**

We have completed our review of this application as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the Medication Guide). These revisions are terms of the sNDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 20-998/S-023."

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Lauren Tornetta, Regulatory Project Manager, at (301) 796-2246.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Education 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/

Sharon Hertz
11/2/2007 01:34:36 PM
Signing for Bob Rappaport, M.D.