DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-998/S-021

G.D. Searle L.L.C.
c/o: Pfizer Inc.
235 E. 42nd Street
New York, NY 10017

Attention: Daniel G. Chirby, M.Sc.
Associate Director, Worldwide Regulatory Strategy

Dear Mr. Chirby:

Please refer to your supplemental new drug application dated June 20, 2006, received June 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CELEBREX® (celecoxib), Capsules.

We acknowledge receipt of your submissions dated July 28, August 3, 9, and 29, September 7, October 2, 5, 11, 19, 27, and 30, November 17, and December 6, 12, and 13, 2006.

This supplemental new drug application provides for the use of CELEBREX® (celecoxib) Capsules for the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients 2 years of age and older.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and the text for the Medication Guide.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application for ages 2 to 16 years. We are waiving the pediatric study requirement for this application for ages 0 to 2 years.

Please submit an electronic version of the FPL. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 20-998/S-021**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated December 13, 2006. This commitment is listed below.

1. Blood Pressure/Safety Study in Patients with JRA:

   Protocol Submission Date: by April 30, 2007
   Study Start: by January 31, 2008*
   Final Study Report: by January 31, 2010
   - Pending acceptance of the protocol by the Division

We also remind you of your postmarketing study agreements. These agreements are listed below.

1. Current Pharmacovigilance Plan: ONGOING

2. Proposed Additional Pharmacovigilance Activities:

   a. Active Surveillance:

      At least one survey cycle: by June 30, 2007 – December 31, 2007
      Twice Annually: by January 31, 2008

   b. Prospective Observational Registry:

      Protocol Submission: by June 20, 2007
      Registry Start: by January 01, 2008*
      Final Study Report by December 31, 2012**
      * Pending acceptance of the protocol by the Division
      **Contingent upon ability to recruit and retain an adequate number of patients.

   c. Independent Pediatric Expert Panel:

      Implemented: by June 30, 2007

      It is anticipated that the Panel will meet initially on a twice-yearly basis or more frequently if consultation for urgent or ad hoc safety issues is necessary.

Submit clinical protocols to your IND for this product. Submit nonclincal and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(viii), you should include a status summary or each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**," or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

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

Please submit one market package of the drug product when it is available.

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, 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 Evaluation and Research

Enclosure

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

/s/

Bob Rappaport

12/15/2006 05:32:50 PM