DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-998/S-018
NDA 20-998/S-019

Pfizer Global Pharmaceuticals
235 E. 42nd Street
New York, NY 10017

Attention: Robert B. Clark
Vice President, US Regulatory Affairs

Dear Mr. Clark:

Please refer to your supplemental new drug applications dated September 30, 2004, received October 1, 2004 (S-018), and June 24, 2005, received June 28, 2005 (S-019), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celebrex® (celecoxib) Capsules.

We acknowledge receipt of your submissions dated January 27, March 16, April 29, May 17, June 3, and July 5, 12, 14, and 28, 2005 (S-018).

Supplement S-018 provides for the additional indication for use of Celebrex® (celecoxib) capsules for the relief of signs and symptoms of ankylosing spondylitis.

Supplement S-019 provides for revised package insert to include a boxed warning, additional information about cardiovascular risks, and a MedGuide as requested by the Agency in the June 14, 2005 letter.

We have completed our review of these applications, as amended, and they are 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 labeling text for the package insert submitted July 28, 2005, and the text for the Med Guide submitted July 24, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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-018, S-019**." Approval of this submission(s) by FDA is not required before the labeling is used.

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 are waiving the pediatric study requirement for ages 0 to 16 years.

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 the Division of Anesthesia, Analgesia and Rheumatology Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
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, call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

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
7/29/05 02:04:44 PM
Signing for Bob Rappaport, M.D.