DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 11-757/S-085, S-086

Pfizer Global Research & Development
235 East 42nd Street
New York, NY 10017

Attention: Tricia Douglas, MS, RAC
Regulatory Manager
Worldwide Regulatory Strategy

Dear Ms. Douglas:

Please refer to your supplemental new drug applications dated May 2, 2007, received May 3, 2007, submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act for Depo-Medrol (methylprednisolone acetate injectable suspension, USP) with Benzyl Alcohol (S-085) and Depo-Medrol (methylprednisolone acetate injectable suspension, USP) with Myristyl-Gamma-Picolinium Chloride (S-086).

We acknowledge receipt of your submissions dated July 25, 2008 (S-085) and September 18, 2008 (S-086).

Reference is also made to the Agency's July 6, 2001, Approvable letter for multiple labeling supplements submitted between July 27, 1987, and December 21, 1995.

These supplemental new drug applications provide for revisions requested in the July 6, 2001, Approvable letter, and additional changes/revisions to most of the sections of the package insert based on more current information.

We have completed our review of these applications, as amended. These applications are 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 21 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. 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 sNDA 11-757/S-085 and sNDA 11-757/S-086."

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, call Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob A. 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/

Sharon Hertz
4/7/2009 01:24:22 PM
Signing for Bob Rappaport, M.D.