DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 011856/S-107 **SUPPLEMENT APPROVAL**

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 application dated June 9, 2010, received June 9, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Solu-Medrol (methylprednisolone sodium succinate for injection, USP).

Reference is also made to the Agency's April 10, 2001, Approvable letter for multiple labeling supplements submitted between June 13, 1983, and June 9, 1997, and approval letters dated April 7, 2009, for Depo-Medrol/NDA 11-757/S-085 and S-086, and September 1, 2009, for Solu-Cortef/NDA 9-866/S-077 and S-079.

This supplemental new drug application provides for revisions to the multiple sections of the Package Insert, to conform with the recently approved labels for the injectable corticosteroids.

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

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.

LETTERS TO HEALTH CARE PROFESSIONALS

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

REPORTING REQUIREMENTS

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 Jessica Benjamin, Regulatory Project Manager, at (301) 796-3924.

Sincerely,

{See appended electronic signature page}

Badrul Chowdhury, M.D.
Division of Pulmonary, Allergy
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-11856	SUPPL-107	PHARMACIA AND UPJOHN CO	SOLU-MEDROL

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

/s/

LYDIA I GILBERT MCCLAIN
06/24/2010
Deputy Division Director