# Drugs@FDA: FDA Approved Drug Products



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**New Drug Application (NDA):** 011856
**Company:** PHARMACIA AND UPJOHN



## Products on NDA 011856

CSV Excel Print

| Drug Name | Active Ingredients | Strength | Dosage Form/Route |
|---|---|---|---|
| SOLU-MEDROL | METHYLPREDNISOLONE SODIUM SUCCINATE | EQ 40MG BASE/VIAL | INJECTABLE;INJECTION |
| SOLU-MEDROL | METHYLPREDNISOLONE SODIUM SUCCINATE | EQ 125MG BASE/VIAL | INJECTABLE;INJECTION |
| SOLU-MEDROL | METHYLPREDNISOLONE SODIUM SUCCINATE | EQ 500MG BASE/VIAL | INJECTABLE;INJECTION |
| SOLU-MEDROL | METHYLPREDNISOLONE SODIUM SUCCINATE | EQ 1GM BASE/VIAL | INJECTABLE;INJECTION |
| SOLU-MEDROL | METHYLPREDNISOLONE SODIUM SUCCINATE | EQ 2GM BASE/VIAL | INJECTABLE;INJECTION |

Showing 1 to 5 of 5 entries

## Approval Date(s) and History, Letters, Labels, Reviews for NDA 011856

## Labels for NDA 011856

## Therapeutic Equivalents for NDA 011856

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**U.S. Food and Drug Administration**
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Contact FDA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011856/S-103 and S-104

**SUPPLEMENT APPROVAL**

Pfizer Inc.
235 East 42nd Street
New York, NY 10017-5755

Attention: Michele Burtness
Worldwide Regulatory Strategy

Dear Ms. Burtness:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received September 11, 2009 (S-103), and October 23, 2009 (S-104), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Solu-Medrol (methylprednisolone sodium succinate for injection, USP).

We acknowledge receipt of your amendment(s) dated October 23, 2009, and January 24(2) 2011, for S-103, and August 19, 2011, for S-103 and S-104.

Supplement S-103 proposes removal of the preservative benzyl alcohol from the top chamber diluent of the Act-O-Vial (AOV) presentations for Solu-Medrol and revised container labels.

Supplement S-104 proposes for revised Package Insert to include preservative-free presentations of Solu-Medrol.

We have completed our review of this supplemental application, as amended. It is 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 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your August 19, 2011, submission containing final printed carton and container labels.

## PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

## REPORTING REQUIREMENTS

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 Michelle Jordan-Garner, Regulatory Project Manager, at (301) 796-4786.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

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/s/

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LYDIA I GILBERT MCCLAIN
10/20/2011
Acting Division Director