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New Drug Application (NDA): 011757
Company: PHARMACIA AND UPJOHN

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Products on NDA 011757

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Drug Name	Active Ingredients	Strength	Dosage Form/Route
DEPO-MEDROL	METHYLPREDNISOLONE ACETATE	40MG/ML	INJECTABLE;INJECTION
Marketing Status Prescription TE CodeAB RLDYes RSYes			
DEPO-MEDROL	METHYLPREDNISOLONE ACETATE	20MG/ML	INJECTABLE;INJECTION
DEPO-MEDROL	METHYLPREDNISOLONE ACETATE	80MG/ML	INJECTABLE;INJECTION

Showing 1 to 3 of 3 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 011757

- Labels for NDA 011757
- Therapeutic Equivalents for NDA 011757

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U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 11757/S-111

SUPPLEMENT APPROVAL

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

Attention: Shai Srulovich, RPh, PharmD
Director, Pfizer Essential Health Global Regulatory Affairs R & D

Dear Dr. Srulovich:

Please refer to your Supplemental New Drug Application (sNDA) dated January 19, 2017, received January 19, 2017 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Depro-Medrol (methyl/prednisolone acetate) Injectable Suspension.

This Prior Approval supplemental new drug application provides for updates to the carton and container labeling to revise the font style/size/color of the proprietary name, to include tall man lettering in the established name and to include the total quantity per total volume.

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **“Final Printed Carton and Container Labels for approved NDA 11757/S-111.”** Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Carol F. Hill, Senior Regulatory Health Project Manager for Safety, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy and Rheumatology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:

Carton and Container Labeling

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

/s/

SALLY M SEYMOUR
03/15/2017