Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 011153
Company: PHARMACIA AND UPJOHN

Products on NDA 011153

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status
MEDROL	METHYLPREDNISOLONE	4MG	TABLET;ORAL	Prescriptio
MEDROL	METHYLPREDNISOLONE	2MG	TABLET;ORAL	Prescriptio
MEDROL	METHYLPREDNISOLONE	16MG	TABLET;ORAL	Prescriptio
MEDROL	METHYLPREDNISOLONE	8MG	TABLET;ORAL	Prescriptio
MEDROL	METHYLPREDNISOLONE	24MG	TABLET;ORAL	Discontinue
MEDROL	METHYLPREDNISOLONE	32MG	TABLET;ORAL	Prescriptio

Showing 1 to 6 of 6 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 011153

Labels for NDA 011153

Therapeutic Equivalents for NDA 011153

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011153/S-075

SUPPLEMENT APPROVAL

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

Attention: Shai Srulovich, PharmD, RPh
Director, Pfizer Essential Health, GRA Brands

Dear Dr. Srulovich:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 24, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Medrol (methylprednisolone, USP) Tablets.

This "Changes Being Effected" supplemental new drug application proposes to update the Precautions section of the Prescribing Information concerning scleroderma renal crisis in patients with systemic sclerosis.

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.

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 prescribing information), 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 that include labeling changes 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).

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 Christine Ford, Regulatory Project Manager, at (301) 796-3420.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SALLY M SEYMOUR
07/24/2018