CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 020246/S-050

Trade Name: **DEPO-PROVERA**

Generic Name: **Medroxyprogesterone Acetate**

Sponsor: **Pharmacia & Upjohn**

Approval Date: 09/27/2013

Indications: Depo-Provera CI is indicated only for the prevention of pregnancy.

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APPLICATION NUMBER:

NDA 020246/S-050

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APPLICATION NUMBER:

NDA 020246/S-050

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 09866/S-097 plus 17 others

APPROVAL LETTER

Pharmacia and Upjohn Company
Attention: Kathleen Collins
Senior Manager Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

Dear Ms. Collins:

Please refer to your Supplemental New Drug Applications (sNDAs) dated June 7, 2013, received June 7, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA/ Supplement	Drug Product	Date of Submission	Date of Receipt
09866/S-097	Solu-Cortef ® (hydrocortisone sodium succinate) Sterile Powder for Injection	June 7, 2013	June 7, 2013
11757/S-099	Depo-Medrol ® (methylprednisolone acetate) Injectable Suspension	June 7, 2013	June 7, 2013
11856/S-117	Solu-Medrol ® (methylprednisolone sodium succinate) Sterile Powder for Injection	June 7, 2013	June 7, 2013
12541/S-079	Depo-Provera ® (medroxyprogesterone acetate) Sterile Aqueous Suspension	June 7, 2013	June 7, 2013
17989/S-020	Hemabate ® (carboprost tromethamine) Sterile Solution	June 7, 2013	June 7, 2013
18484/S-025	Prostin VR Pediatric ® (alprostadil) Sterile Solution	June 7, 2013	June 7, 2013
20246/S-050	Depo-Provera ® (medroxyprogesterone acetate) Injectable Suspension	June 7, 2013	June 7, 2013
20379/S-025	Caverject ® (aloprostadil) Sterile Powder for Injection	June 7, 2013	June 7, 2013
20450/S-022	Cerebyx ® (fosphenytoin sodium) Injection	June 7, 2013	June 7, 2013
20491/S-008	Corvert ® (ibutilide fumarate) Injection	June 7, 2013	June 7, 2013
20571/S-046	Camptostar ® (irinotecan hydrochloride) Injection	June 7, 2013	June 7, 2013

20919/S-034	Geodon ® (ziprasidone hydrochloride) Capsules	June 7, 2013	June 7, 2013
21267/S-043	Vfend ® (voriconazole) IV for Injection	June 7, 2013	June 7, 2013
21632/S-018	Eraxis ® (anidulafungin) Injection	June 7, 2013	June 7, 2013
50317/S-0176	Lincocin ® (lincomycin hydrochloride) Sterile Solution for Injection	June 7, 2013	June 7, 2013
50441/S-065	Cleocin Phosphate ® (clindamycin phosphate) Sterile Solution	June 7, 2013	June 7, 2013
50733/S-036	Zithromax ® (azithromycin) IV for Injection	June 7, 2013	June 7, 2013
201370/S-006	Heparin Sodium Injection	June 7, 2013	June 7, 2013

These "Prior Approval" supplemental new drug applications provide for a comparability protocol for the Kalamazoo (b) (4). The (b) (4) project is designed to (b) (4) facility.

We have completed our review of these supplemental new drug applications. These supplements are approved.

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 Navdeep Bhandari, Regulatory Health Project Manager, at (240) 402-3815.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, Ph.D.
Branch Chief, Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

THOMAS F OLIVER
09/27/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 020246/S-050

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER,	SUPPORTING DOC. #
	DAAAP	**09-866**	195

3. NAME AND ADDRESS OF APPLICANT	4. COMMUNICATION, DATE	
Pfizer 235 East 42nd Street New York, NY 10017-5755 212 733-4529	Supplement no: Submission type: Letter date: Stamp date: ONDQA receipt: PDUFA date:	**S-097 (bundle)** **PA** 7-Jun-2013 7-Jun-2013 20-Jun-2013 **7-Oct-2013**

5. PROPRIETARY NAME:	6. ESTABLISHED NAME:	7. AMENDMENTS, REPORT, DATE:
Solu-Cortef	Hydrocortisone sodium succinate, USP	N/A

8. SUPPLEMENT PROVIDES FOR:

a (b) (4) for the Kalamazoo (b) (4). The (b) (4) project is designed to (b) (4) facility. The changes to the (b) (4) are not product specific.

9. PHARMACOLOGICAL CLASS:	10. HOW DISPENSED:	11. RELATED/BUNDLED DOCs:
Analgesic Steroid	Rx	**50-317/S-176; 11-856/S-117; 50-441/S-065; 21-632/S-018; 50-733/S-036; 11-757/S-099; 20-450/S-022; 20-491/S-008; 18-484/S-025; 17-989/S-020; 201-370/S-006; 20-571/S-046; 20-919/S-034; 20-379/S-025; 20-246/S-050; 12-541/S-079; 21-267/S-043**
12. DOSAGE FORM:	**13. POTENCY:**	
Sterile powder for injection	100, 250, 500, 1000 mg/vial	

14. CHEMICAL NAME AND STRUCTURE:

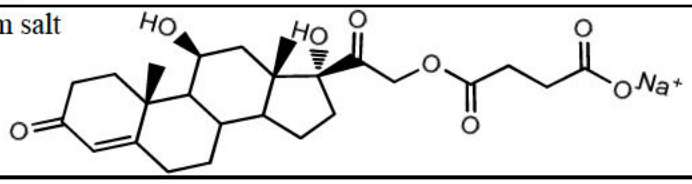
USAN name: Hydrocortisone sodium succinate, USP

IUPAC name: 11β,17α,21-Trihydroxy-4-pregnene-3,20-dione 21-hemisuccinate sodium salt

Molecular formula: $C_{25}H_{33}NaO_8$ Molecular weight: 484.51 g/mol

CAS [125-04-2] Company in-house code: None

Chemical structure: hydrocortisone succinate sodium salt



15. COMMENTS:

a comparability protocol for the Kalamazoo (b) (4). The (b) (4) project is designed to (b) (4) facility. The processes of re-qualifying and validating the impacted areas are adequately described and conform to all regulatory requirements, guidelines and guidances.

16. CONCLUSION AND RECOMMENDATION

APPROVAL

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
Christopher Hough, Ph.D.	See appended electronic signature sheet	24-Sep-2013

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

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/s/

CHRISTOPHER J HOUGH
09/26/2013

THOMAS F OLIVER
09/27/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 020246/S-050

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CMC MICRO & STERILITY ASSURANCE REVIEW REQUEST

TO *(Division/Office)*: **New Drug Microbiology Staff**

E-mail to: **CDER OPS IO MICRO**

Paper mail to: **WO Bldg 51, Room 4193**

FROM: Navi Bhandari

PROJECT MANAGER *(if other than sender)*:

REQUEST DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
June 25, 2013		09866/S-097 **plus 17 others**		June 7, 2013

NAMES OF DRUG	PRIORITY CONSIDERATION	PDUFA DATE	DESIRED COMPLETION DATE
Solu-Cortef Depo-Medrol Solu-Medrol Depo-Provera Hemabate Prostin VR Pediatric Depo-Provera Caverject Cerebyx Corvert Camptostar Geodon Vfend Eraxis Lincocin Cleocin Phosphate Zithromax Heparin Sodium Injection	**PAS**	October 7, 2013	September 7, 2013

NAME OF APPLICANT OR SPONSOR: Pharmacia & Upjohn Company

GENERAL PROVISIONS IN APPLICATION

- ☐ 30-DAY SAFETY REVIEW NEEDED
- ☐ NDA FILING REVIEW NEEDED BY: _____
- ☐ BUNDLED
- ☐ DOCUMENT IN EDR
- ☐ CBE-0 SUPPLEMENT
- ☐ CBE-30 SUPPLEMENT
- ☐ CHANGE IN DOSAGE, STRENGTH / POTENCY

COMMENTS / SPECIAL INSTRUCTIONS:

NDA 09866/S-097, 11757/S-099, 11856/S-117, 12541/S-079, 17989/S-020, 18484/S-025, 20246/S-050, 20379/S-025, 20450/S-022, 20491/S-008, 20571/S-046, 20919/S-034, 21267/S-043, 21632/S-018, 50317/S-0176, 50441/S-065, 50733/S-036, 201370/S-006:

Provides for a comparability protocol for the Kalamazoo (b) (4) project. The (b) (4) project is designed to (b) (4) facility. The changes to the (b) (4) are not product specific.

Reference ID: 3331324

APPEARS THIS WAY
ON ORIGINAL

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/s/

NAVDEEP BHANDARI
06/25/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 09866/S-097 plus 17 others

ACKNOWLEDGEMENT --
PRIOR APPROVAL SUPPLEMENT

Pharmacia and Upjohn Company
Attention: Kathleen Collins
Senior Manager Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

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201370/S-006	Heparin Sodium Injection	June 7, 2013	June 7, 2013

These supplemental applications propose a comparability protocol for the Kalamazoo [redacted (b) (4)] project. The [redacted (b) (4)] project is designed to upgrade the [redacted (b) (4)] facility.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on August 6, 2013, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 7, 2013.

SUBMISSION REQUIREMENTS

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Transplant and Ophthalmology
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have questions, call me, at (240) 402-3815.

Sincerely,

{See appended electronic signature page}

Navdeep Bhandari
Regulatory Health Project Manager
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

NAVDEEP BHANDARI
06/25/2013