CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 020246/S-052

Trade Name: **DEPO-PROVERA**

Generic Name: **Medroxyprogesterone Acetate**

Sponsor: **Pharmacia & Upjohn**

Approval Date: 06/09/2014

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

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CONTENTS

Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

NDA 020246/S-052

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 09866/S-102 plus 17 others

APPROVAL LETTER

Pharmacia & Upjohn Company
Attention: Karen Baker
Director, Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

Dear Ms. Baker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 31, 2014, received January 31, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Supplement Number	Product Name
09866	S-102	Solu-Cortef® (hydrocortisone sodium succinate) Powder for Injection
11757	S-102	Depo Medrol® (methylprednisolone acetate) Injectable Suspension
11856	S-122	Solu-Medrol® (methylprednisolone sodium succinate) Sterile Powder for Injection
12541	S-082	Depo-Provera® (medroxyprogesterone acetate) Sterile Aqueous Injection
17989	S-022	Hemabate® (carboprost tromethamine) Sterile Solution
18484	S-026	Prostin VR Pediatric® (alprostadil) Injection
20246	S-052	Depo-Provera® (medroxyprogesterone acetate) Contraceptive Injection
20379	S-027	Caverject® (alprostadil) Sterile Powder for Injection
20450	S-026	Cerbyx® (fosphenytoin sodium) Injection
20491	S-009	Corvert® (ibutilide fumarate) Injection
20571	S-047	Camptosar® (irinotecan hydrochloride) Injection
20919	S-039	Geodon® (ziprasidone mesylate) Injection
21267	S-045	Vfend® (voriconazole) Solution for Injection
21632	S-020	Eraxis® (anidulafungin) Injection
50317	S-178	Lincocin® (lincomycin hydrochloride) Injection

50733	S-037	Zithromax® (azithromycin) Powder for Injection
50441	S-069	Cleocin Phosphate® (clindamycin) Injection
201370	S-007	Heparin Sodium Injection

These "Changes Being Effected" supplemental new drug applications provide for approval of the APS pressurization upgrade.

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
06/09/2014

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 020246/S-052

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER,	SUPPORTING DOC. #
	HFD-520	**09-866**	208

3. NAME AND ADDRESS OF APPLICANT	4. COMMUNICATION, DATE	
Pfizer Inc. 235 East 42nd Street New York, NY 10017-5755 423 989-8178 Karen Baker	Supplement no: Submission type: Letter date: Stamp date: ONDQA receipt: PDUFA date:	**S-102** **CBE-0** 28-Feb-2014 28-Feb-2014 26-Mar-2014 **28-Jun-2014**

5. PROPRIETARY NAME:	6. ESTABLISHED NAME:	7. AMENDMENTS, REPORT, DATE:
Solu-Cortef	Hydrocortisone Sodium Succinate	None

8. SUPPLEMENT PROVIDES FOR: approval of the APS pressurization upgrade

9. PHARMACOLOGICAL CLASS:	10. HOW DISPENSED:	11. RELATED/BUNDLED DOCs:
Corticosteroid salt	Rx	21267/S-045; 50733/S-037; 20571/S-047; 50441/S--069; 11757/S-102; 20379/S027; 20491/S-009; 20246/S-052; 17989/S-022; 12541/S-082; 11856/S-122; 50317/S-178; 20919/S-039; 18484/S-026; 21632/S020; 201370/S-007; 20450/S-026
12. DOSAGE FORM:	**13. POTENCY:**	
injectable, injection	100, 250, 500, 1000 mg base/vial	

14. CHEMICAL NAME AND STRUCTURE:

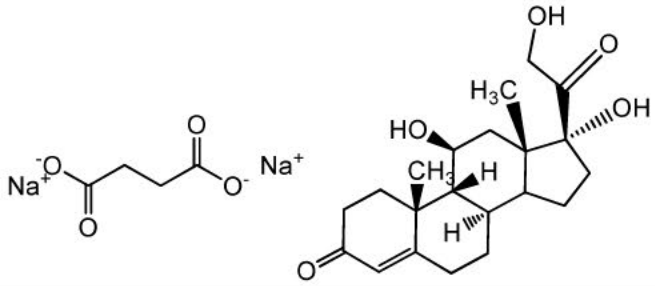
USAN name: Hydrocortisone Sodium Succinate

IUPAC name: Pregn-4-ene-3,20-dione, 21-(3-carboxy-1-oxopropoxy)-11,17-dihydroxy-, monosodium salt, (11β)-

Molecular formula: C25H33NaO8 Molecular weight: 484.51 g/mol

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

Chemical structure:



15. COMMENTS: NDA 09-866 S-102 is a CBE-0 supplement providing for approval of the APS pressurization upgrade. The comparability protocol was adequately described and qualified for intended purpose. Microbiologist Neal Sweeney recommended approval from the microbiology perspective.

16. CONCLUSION AND RECOMMENDATION

APPROVAL

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
Christopher Hough, Ph.D.	See appended electronic signature sheet	12-May-2014

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

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/s/

CHRISTOPHER J HOUGH
06/09/2014

THOMAS F OLIVER
06/09/2014

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 020246/S-052

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADM NISTRATION

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
2/25/2014		09866/S-102 plus 17 others	Electronic	1/31/2014

NAMES OF DRUG	PRIORITY CONSIDERATION	PDUFA DATE	DESIRED COMPLETION DATE
Solu-Cortef® plus 17 others	**CBE-30**	7/31/2014	6/30/2014

NAME OF APPLICANT OR SPONSOR: Pharmacia & Upjohn

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-102, 11757/S-102, 11856/S-122, 12541/S-082, 17989/S-022, 18484/S-026, 20246/S-052, 20379/S-027, 20571/S-047, 20919/S-039, 21267/S-045, 201370/S-007, 50441/S-069, 21632/S-020, 50317/S-178, 50733/S-037, 20450/S-026, 20491/S-009

Provides for changes in the comparability protocol.

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\\cdsesub1\evsprod\nda009866\0044\m1\us\356h.pdf

SIGNATURE OF REQUESTER

REVIEW REQUEST DELIVERED BY (Check one):

☐ DARRTS ☐ EDR ☐ E-MAIL ☐ MAIL ☐ HAND

DOCUMENTS FOR REVIEW DELIVERED BY (Check one):

☐ EDR ☐ E-MAIL ☐ MAIL ☐ HAND

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/s/

NAVDEEP BHANDARI
02/25/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 09866/S-102 plus 17 others

CBE SUPPLEMENT – ACKNOWLEDGEMENT

Pharmacia & Upjohn Company
Attention: Karen Baker
Director, Worldwide Safety and Regulatory
235 East 42nd Street
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Dear Ms. Baker:

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NDA Number	Supplement Number	Product Name	Receipt Date
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11856	S-122	Solu-Medrol® (methylprednisolone sodium succinate) Sterile Powder for Injection	1/31/2014
12541	S-082	Depo-Provera® (medroxyprogesterone acetate) Sterile Aqueous Injection	1/31/2014
17989	S-022	Hemabate® (carboprost tromethamine) Sterile Solution	1/31/2014
18484	S-026	Prostin VR Pediatric® (alprostadil) Injection	1/31/2014
20246	S-052	Depo-Provera® (medroxyprogesterone acetate) Contraceptive Injection	1/31/2014
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21632	S-020	Eraxis® (anidulafungin) Injection	1/31/2014
50317	S-178	Lincocin® (lincomycin hydrochloride) Injection	1/31/2014

50733	S-037	Zithromax® (azithromycin) Powder for Injection	1/31/2014
50441	S-069	Cleocin Phosphate® (clindamycin) Injection	1/31/2014
201370	S-007	Heparin Sodium Injection	1/31/2014

These supplemental applications, submitted as "Changes Being Effected" supplements, provide for approval of the APS pressurization upgrade

Unless we notify you within 60 days of the receipt date that these applications are not sufficiently complete to permit a substantive review, we will file the applications on April 1, 2014, in accordance with 21 CFR 314.101(a). If these applications are filed, the user fee goal date will be July 31, 2014.

Cite the application numbers listed above at the top of the first page of all submissions to these applications. 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 Anti-Infective Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Sincerely,

{See appended electronic signature page}

Navi Bhandari, Pharm.D
Regulatory Health Project Manager
Office of Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

NAVDEEP BHANDARI
02/25/2014