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.

APPLICATION NUMBER: NDA 020246/S-052

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APPLICATION NUMBER: NDA 020246/S-052

APPROVAL LETTER



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	Supplement	Product Name			
Number	Number				
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

/s/

THOMAS F OLIVER 06/09/2014

APPLICATION NUMBER: NDA 020246/S-052

CHEMISTRY REVIEW(S)

NDA 09-866 S-102 Review

HFD-52009-8662083. NAME AND ADDRESS OF APPLICANT4. COMMUNICATION, DATEPfizer Inc.Supplement no:S-102235 East And StreetSubmission type:CBE-0New York, NY 10017-5755Letter date:28-Feb-2014423 989-8178 Karen BakerStamp date:28-Feb-2014900 PZ date:28-Feb-201428-Feb-20145. PROPRIETARY NAME:6. ESTABLISHED NAME: Hydrocortisone Sodium Succinate7. AMENDATENTS, REPORT, DATE: None8. SUPPLEMENT PROVIDES FOR: approval of the APS pressurization upgrade9. PHARMACOLOGICAL CLASS:10. HOW DISPENSED: 11. RELATED/BUNDLED DOCs: 21267/S-045; 50733/S-037; 20571/S-047; 20441/S-069; 2175/S-102; 20379/S027; 20441/S-069; 2175/S040; 20379/S027; 20441/S-069; 2175/S040; 20379/S027; 20441/S-069; 2175/S040; 20379/S027; 20441/S-069; 217	CHEMISTS REVIEW	1. ORGANIZATION 2. NDA NUMBER		BER,	SUPPORTING DOC. #		
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DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE		Christopher Hough, Ph.D. See appended electronic signature sheet 12-May-2014			12-May-2014		
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6 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

/s/

CHRISTOPHER J HOUGH 06/09/2014

THOMAS F OLIVER 06/09/2014

APPLICATION NUMBER: NDA 020246/S-052

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADM NISTRATION			MC MICRO & STERILITY ASSURANCE REVIEW REQUEST			
TO (Division/Office): New Drug Microbiology Staff			FROM: Navi Bhandari			
<i>E-mail to:</i> CDER OPS IO MIC		CRO				
Paper mail	to: WO B	ldg 51, Ro	oom 4193	PROJECT MANAGE	ER (if other than send	der):
request date 2/25/2014	IND NO.		NDA NO. 09866/S-102 plus 17 others	TYPE OF DOCUMENT Electronic		DATE OF DOCUMENT 1/31/2014
NAMES OF DRUG Solu-Cortef® plus 17 o	thers	PRIORITY CO	ONSIDERATION	PDUFA DATE DESIRED COMPLETION DATE 6/30/2014		
NAME OF APPLICANT OR SPONS	or: Pharm	acia & U	Jpjohn			
			GENERAL PROVISIO	ONS IN APPLICATION		
□ 30-DAY 5	SAFETY REVIE	W NEEDED			CBE-0 SUPPLEMENT	
D NDA FILI	EEDED BY:		CBE-30 SUPPLEMENT			
					CHANGE IN DOSAGE	E, STRENGTH / POTENCY
	ENT IN EDR					
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. \\cdsesub1\evsprod\nda009866\0044\m1\us\cover.pdf						
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SIGNATURE OF REQUESTER				REVIEW REQUEST	DELIVERED BY (Check	one):
				D DA	RRTS 🗆 EDR 🗆	E-MAIL 🗆 MAIL 🗆 HAND
				DOCUMENTS FOR	REVIEW DELIVERED B	Y (Check one):
						Mail 🗆 Mail 🗆 Hand

/s/

NAVDEEP BHANDARI 02/25/2014



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 New York, NY 10017

Dear Ms. Baker:

We have received your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA	Supplement	Product Name	Receipt Date
Number	Number		-
09866	S-102	Solu-Cortef [®] (hydrocortisone sodium	1/31/2014
		succinate) Powder for Injection	
11757	S-102	Depo Medrol [®] (methylprednisolone	1/31/2014
		acetate) Injectable Suspension	
11856	S-122	Solu-Medrol [®] (methylprednisolone	1/31/2014
		sodium succinate) Sterile Powder for	
		Injection	
12541	S-082	Depo-Provera [®] (medroxyprogesterone	1/31/2014
		acetate) Sterile Aqueous Injection	
17989	S-022	Hemabate [®] (carboprost tromethamine)	1/31/2014
		Sterile Solution	
18484	S-026	Prostin VR Pediatric® (alprostadil)	1/31/2014
		Injection	
20246	S-052	Depo-Provera [®] (medroxyprogesterone	1/31/2014
		acetate) Contraceptive Injection	
20379	S-027	Caverject [®] (alprostadil) Sterile Powder	1/31/2014
		for Injection	
20450	S-026	Cerbyx [®] (fosphenytoin sodium) Injection	1/31/2014
20491	S-009	Corvert [®] (ibutilide fumarate) Injection	1/31/2014
20571	S-047	Camptosar [®] (irinotecan hydrochloride)	1/31/2014
		Injection	
20919	S-039	Geodon [®] (ziprasidone mesylate) Injection	1/31/2014
21267	S-045	Vfend [®] (voriconazole) Solution for	1/31/2014
		Injection	
21632	S-020	Eraxis [®] (anidulafungin) Injection	1/31/2014
50317	S-178	Lincocin [®] (lincomycin hydrochloride)	1/31/2014
		Injection	

50733	S-037	Zithromax [®] (azithromycin) Powder for	1/31/2014
		Injection	
50441	S-069	Cleocin Phosphate [®] (clindamycin)	1/31/2014
		Injection	
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

/s/

NAVDEEP BHANDARI 02/25/2014