CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 020246/S-049

Trade Name: **DEPO-PROVERA**

Generic Name: **Medroxyprogesterone Acetate**

Sponsor: **Pharmacia & Upjohn**

Approval Date: 09/10/2013

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

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APPLICATION NUMBER:

NDA 020246/S-049

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

NDA 020246/S-049

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19617/S-016 and 5 others

APPROVAL LETTER

Pharmacia & Upjohn Company
c/o Pfizer Inc.
Attention: Michele Burtness, Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Burtness:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received March 15, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Drug Product	Supplement
19617	Prepidil® (dinoprostone) Cervical Gel	016
19281	Cyklokapron® (tranexamoc acid) Injection	032
20246	Depo-Provera® (medroxyprogesterone acetate) Contraceptive Injection	049
21583	Depo Sub-Q Provera 104® (medroxyprogesterone acetate) Suspension for Injection	022
20597	Xalatan® (latanoprost) Ophthalmic Solution 0.005%	047
21106	Somavert® (pegvisomant for injection)	041

These "Changes Being Effected" supplemental applications provide for a change in the (b) (4) at the Pfizer (b) (4) manufacturing facility located in Puurs, Belgium.

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 LCDR Kerri-Ann Jennings, Regulatory Health Project Manager, at (301) 796-2919.

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
09/10/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 020246/S-049

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW # 1	**1. ORGANIZATION** HFD-580	**2. NDA NUMBER** **19-617/S-016 CBE-30** **20-246/ S-049** **21-583/ S-022** **19/281/ S-032** **20-597/ S-047** **21-106/ S-041**
3. NAME AND ADDRESS OF APPLICANT ***(City and State)*** Pfizer Inc 235 East 42ne street New York, NY 10017-5755		**4. AF NUMBER** **5. SUPPLEMENT(S)** NUMBER(S) DATES(S) Letter date: 3/15/13 Receive date: 3/15/13 Goal date: 9/15/13
6. NAME OF DRUG: Prepidil® (dinoprostone) gel	**7. NONPROPRIETARY NAME** Ketoconazole	
8. SUPPLEMENT PROVIDES FOR: A change in the [redacted] (b) (4) at the Pfizer [redacted] (b) (4) manufacturing facility located in Puurs, Belgium.		**9. AMENDMENT(S), REPORT(S), ETC.** NUMBER(S) DATE(S)
10. PHARMACOLOGICAL CATEGORY Ripening an unfavorable cervix in pregnant women at/near term with medical/obstetrical need for labor induction.	**11. HOW DISPENSED** RX X OTC	**12. RELATED IND/NDA/DMF** **Bundled supplements:** **20-246/S-049 3/15/13** **21-583/S-022 3/15/13** **19/281/S-032 3/15/13** **20-597/S-047 3/15/13** **21-106/S-041 3/15/13**
13. DOSAGE FORM(S) Gel	**14. POTENCY** 0.5mg/3gm	
15. CHEMICAL NAME AND STRUCTURE Refer to USAN		**16. RECORDS AND REPORTS** CURRENT YES__NO REVIEWED YES__NO

17. COMMENTS:

A micro review was initiated on 4/26/13 to review the adequacy of the submitted data According to micro review (NAled; dated 5/3/2013), "the changes were assessed using a [redacted] (b) (4) Test,temperature distribution studies and heat penetration/BI challenges studies. The study results were acceptable and demonstrated that the proposed changes had no negative impact on the sterilization cycle,. Therefore, no additional product quality microbiology review is necessary."

18. CONCLUSIONS AND RECOMMENDATIONS:

From CMC standpoint, this supplement is recommended **for approval.**

cc:
Orig. NDA 19-617/S-016 bundle
HFD-580/div. File
doc # N:\NDA\19-617\S-016\Chem\09.05.13. REV

19. REVIEWR NAME:	**SIGNATURE**	**DATE COMPLETED**
Hossein S. Khorshidi		9/5/2013

1 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

HOSSEIN S KHORSHIDI
09/06/2013

THOMAS F OLIVER
09/06/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 020246/S-049

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

19617/S-016 and 5 others

CBE SUPPLEMENT – ACKNOWLEDGEMENT

Pharmacia & Upjohn Company
c/o Pfizer Inc.
Attention: Michele Burtness, Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Burtness:

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	Drug Product	Date of Submission	Date of Receipt
19617/S-016	Prepidil® (dinoprostone) Cervical Gel	March 15, 2013	March 15, 2013
19281/S-032	Cyklokapron® (tranexamoc acid) Injection	March 15, 2013	March 15, 2013
20246/S-049	Depo-Provera® (medroxyprogesterone acetate) Contraceptive Injection	March 15, 2013	March 15, 2013
21583/S-022	Depo Sub-Q Provera 104® (medroxyprogesterone acetate) Suspension for Injection	March 15, 2013	March 15, 2013
20597/S-047	Xalatan® (latanoprost) Ophthalmic Solution 0.005%	March 15, 2013	March 15, 2013
21106/S-041	Somavert® (pegvisomant for injection)	March 15, 2013	March 15, 2013

These supplemental applications, submitted as "Changes Being Effected" supplements, propose the following change: A change in the [redacted (b) (4)] at the Pfizer [redacted (b) (4)] manufacturing facility located in Puurs, Belgium.

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 May 14, 2013, in accordance with 21 CFR 314.101(a). If these applications are filed, the user fee goal date will be September 15, 2013.

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 Bone, Reproductive and Urologic Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, please call me at (301) 796-2919.

Sincerely,

{See appended electronic signature page}

Kerri-Ann Jennings, MS, BSN, RN
Regulatory Health Project Manager
Office of New Drug Quality Assessment II
Center for Drug Evaluation and Research

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/s/

KERRI-ANN JENNINGS
06/17/2013

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: Kerri-Ann Jennings- X62919 ONDQA PM
CMC Reviewer- Hossein Khorshidi

PROJECT MANAGER *(if other than sender):*

REQUEST DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
26 APR 2013		19617/S-16	CMC CBE 0 (electronic)	15 MAR 2013

NAMES OF DRUG	PRIORITY CONSIDERATION	PDUFA DATE	DESIRED COMPLETION DATE
Prepidil®		15 SEPT 2013	15 AUG 2013

NAME OF APPLICANT OR SPONSOR: Pharmacia and Upjohn Co (Pfizer Inc).

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 19617/S-16 is bundled with NDA 19281/S- 32, 20246/S- 49, 21583/S- 22, 20597/S- 47, 21106/S- 41

These CMC CBE 0 supplements provide for a change in the [redacted] (b) (4) at the Pfizer [redacted] (b) (4) manufacturing facility located in Puurs, Belgium.

Please evaluate from a Microbiology perspective.

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/

KERRI-ANN JENNINGS
04/26/2013