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RESEARCH**

APPLICATION NUMBER:

21-584

PHARMACOLOGY REVIEW(S)

PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number: 21-584

Review number: 1

Sequence number/date/type of submission: 000/12-17-2003/original submission

Information to sponsor: Yes () No (*)

Sponsor and/or agent: Pfizer, Inc

Manufacturer for drug substance: Pharmacia and Upjohn

Reviewer name: Krishan L. Raheja, D.V.M., Ph.D

Division name: DRUDP

HFD #: 580

Review completion date: 2-17-2004

Drug: Medroxyprogesterone acetate injectable suspension, USP (104 mg/0.65 ml), 160 mg/ml

Trade name: none given

Generic name (list alphabetically): depot medroxyprogesterone acetate

Code name: -

Chemical name: 17-hydroxy-6a-methylpregn-4-ene-3,20-dione 17-acetate

CAS registry number: -

Mole file number: -

Molecular formula/molecular weight: C₂₄H₃₄O₄/344.48

Structure: see review of NDA 21-583 dated 6-30-03

Relevant INDs/NDAs/DMFs: IND 61,388; NDA 21-583

Drug class: progestin

Indication: endometriosis

Clinical formulation: same as under NDA 21-583

Route of administration: subcutaneous injection into the anterior thigh or abdomen once every 3 months

Proposed use: as a treatment to relieve pain symptoms caused by endometriosis

Disclaimer: Tabular and graphical information is from sponsor's submission unless stated otherwise.

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PHARMACOLOGY/TOXICOLOGY REVIEW

- I. PHARMACOLOGY:**
See P/T review of NDA 21-583
- II. SAFETY PHARMACOLOGY:**
See P/T review of NDA 21-583
- III. PHARMACOKINETICS/TOXICOKINETICS:**
See P/T review of NDA 21-583
- IV. GENERAL TOXICOLOGY:**
See P/T review of NDA 21-583
- V. GENETIC TOXICOLOGY:**
See P/T review of NDA 21-583
- VI. CARCINOGENICITY:**
See P/T review of NDA 21-583
- VII. REPRODUCTIVE AND DEVELOPMENTAL TOXICOLOGY:**
See P/T review of NDA 21-583
- VIII. SPECIAL TOXICOLOGY STUDIES:**
None submitted
- IX. DETAILED CONCLUSIONS AND RECOMMENDATIONS:**

Conclusions: The proposed formulation under this NDA for endometriosis is similar to that approved under NDA 21-583 for contraception. The dosage, route and the frequency of administration are also similar.

General Toxicology Issues: none

Recommendations: Pharmacology recommends approval of NDA 21-584.

Labeling with basis for findings: Labeling is similar to the currently approved NDA 21-583 for contraception.

- X. APPENDIX/ATTACHMENTS:**

Addendum to review: none

Other relevant materials (Studies not reviewed, appended consults, etc.): none

Any compliance issues: none

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/s/

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