CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-212

MICROBIOLOGY REVIEW

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #3 OF NDA 21-212
17 November 2000

A. 1. NDA 21-212 BC (Amendment #13)
APPLICANT: Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

2. PRODUCT NAME: Caverject® DC (alprostadil for injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a lyophilized preparation for reconstitution and parenteral use.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the treatment and diagnosis of erectile dysfunction (ED) via intracavernosal injection.

B. 1. DATE OF INITIAL SUBMISSION: 20 January 2000

2. DATE OF AMENDMENT: 5 October 2000 (Subject of this Review)

3. RELATED DOCUMENTS: ; NDA 20-379; NDA 20-755; DMF's

4. ASSIGNED FOR REVIEW: 17 November 2000

C. REMARKS: This review addresses the sterility of the alcohol wipes included in the packaging of the drug product. Questions regarding the sterility of these wipes have been raised by the review chemist.

D. CONCLUSIONS: The non-sterile nature of the alcohol wipes have no impact on the sterility of the drug product. These wipes will not have any effect on the safe use of the product.

Paul Stinavage, Ph.D.

cc: Original NDA 21-212
HFD-580/K. Colangelo/J. Salemme/Div. Files
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 17 November 2000
R/D initialed by P. Cooney

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information

/s/

Paul Stinavage
11/17/00 10:02:23 AM
MICROBIOLOGIST
Use of non-sterile alcohol pads included in product kit.

Peter Cooney
11/17/00 10:20:55 AM
MICROBIOLOGIST

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-212
24 October 2000

A. 1. NDA 21-212 BI
APPLICANT: Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

2. PRODUCT NAME: Caverject® DC (alprostadil for injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a lyophilized preparation for reconstitution and parenteral use.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the treatment and diagnosis of erectile dysfunction (ED) via intracavernosal injection.

B. 1. DATE OF INITIAL SUBMISSION: 20 January 2000

2. DATE OF AMENDMENT: 21 September 2000 (Subject of this Review)

3. RELATED DOCUMENTS: ; NDA 20-379; NDA 20-755; DMF's

4. ASSIGNED FOR REVIEW: 20 October 2000

C. REMARKS: The application provides for the manufacture of a dual chambered cartridge presentation of the product at the Lindshagensgatan plant at Stockholm, Sweden.

The product will be manufactured at:

Building 49, Floor 3
Pharmacia AB
Lindhagensgatan 133
Stockholm, Sweden

Two strengths of the drug product will be manufactured. They are 10 and 20 µg strengths.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

Paul Stinavage, Ph.D.

cc: Original NDA 21-212
HFD-580/K. Colangelo/J. Salemme/Div. Files
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 24 October 2000
R/D initialed by P. Cooney

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REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-212
27 July 2000

A. 1. NDA 21-212
APPLICANT: Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

2. PRODUCT NAME: Caverject® DC (alprostadil for injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a lyophilized preparation for reconsititution and parenteral use.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the treatment and diagnosis of erectile dysfunction (ED) via intracavernosal injection.

B. 1. DATE OF INITIAL SUBMISSION: 20 January 2000

2. DATE OF AMENDMENT: 15 June 2000 (included in this Review)

3. RELATED DOCUMENTS: NDA 20-379; NDA 20-755; DMF's

4. ASSIGNED FOR REVIEW: 14 February 2000

C. REMARKS: The application provides for the manufacture of a dual chambered cartridge presentation of the product at the Lindshagensgatan plant at Stockholm, Sweden.

The product will be manufactured at:

Pharmacia AB
Lindhagensgatan 133
Stockholm, Sweden

Two strengths of the drug product will be manufactured. They are 10 and 20 µg strengths.

D. CONCLUSIONS: The application is approvable upon resolution of microbiology concerns. Specific comments are provided in "E. Review Notes" and "List of Microbiology Deficiencies". A satisfactory inspection status should be obtained prior to approval of the application.

Paul Stinavage, Ph.D.

cc: Original NDA 21-212
HFD-580/K. Colangelo/Div. Files
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 27 July 2000
R/D initialed by P. Cooney

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

REQUEST FOR CONSULTATION

TO *(Division/Office)*: HFD-805 Dr. Peter Gooney

FROM: HFD-580 (Division of Reproductive and Urologic Drug Products) Kim Colangelo

DATE:	IND NO.:	NDA NO.:	TYPE OF DOCUMENT:	DATE OF DOCUMENT:
February 1, 2000		21-212	original	January 20, 2000

NAME OF DRUG:	PRIORITY CONSIDERATION:	CLASSIFICATION OF DRUG:	DESIRED COMPLETION DATE
Caverject DC	standard	3/S	August 20, 2000

NAME OF FIRM: Pharmacia & Upjohn

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE–NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*: New NDA

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER:	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER:

TO: J. Stinavage FAX 2/14/00

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: Please inform me of reviewer assignment. Filing meeting pending.

cc: Original NDA 21212
HFD-580/Div. Files
HFD-580/Colangelo

SIGNATURE OF REQUESTER:	METHOD OF DELIVERY (Check one): ☒ MAIL ☐ HAND
SIGNATURE OF RECEIVER:	SIGNATURE OF DELIVERER: