# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 20-755

## MICROBIOLOGY REVIEW(S)

Kumble

DEC 16 1996

REVIEW FOR HFD-520
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
Microbiologist's Review #1 of NDA 20-755
16 December 1996

A. 1. NDA 20-755
APPLICANT: Pharmacia/Upjohn Inc.
7000 Portage Road
Kalamazoo, MI 49001-0199

2. PRODUCT NAMES: Caverject® Injection (alprostadil aqueous injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is supplied in single dose polyethylene ampules containing either 5, 10, 20 μg/mL (1 mL total volume), or 40 μg/2 mL.

4. METHODS OF STERILIZATION:
The drug product is filled.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the diagnosis and treatment of male erectile dysfunction.

B. 1. DATE OF INITIAL SUBMISSION: 26 July 1996

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS:

| | |
|---|---|
| IND | IND |
| NDA 20-379 | NDA 18-484 |
| DMF | DMF |

4. ASSIGNED FOR REVIEW: 23 August 1996

C. REMARKS: The application is for a sterile, isotonic solution of alprostadil in polyethylene ampules. Each ampule will be packaged in an individual foil blister pack. For each dose of product a pouch containing one empty 2 mL plastic syringe, one individual packaged 27 gauge ½ inch needle and one alcohol swab will be supplied.

The product is to be stored frozen at the pharmacy and may be stored for one month under refrigeration after dispensing.

The product will be manufactured for the applicant by:

is responsible for the release of product for sale, control of the quality assurance program, and for GMP compliance.

D. CONCLUSIONS: The application is approvable upon ~~or~~ the resolution of microbiology concerns.

Paul Stinavage, Ph.D. 16 December 1996

12/16/96

cc: Original NDA 20-755
HFD-580/T. Rumble
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 16 December 1996
R/D initialed by P. Cooney

REVIEW FOR HFD-520
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
Microbiologist's Review #2 of NDA 20-755
2 June 1997

A. 1. NDA 20-755
APPLICANT: Pharmacia/Upjohn Inc.
7000 Portage Road
Kalamazoo, MI 49001-0199

2. PRODUCT NAMES: Caverject® Injection (alprostadil aqueous injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is supplied in single dose polyethylene ampules containing either 5, 10, 20 μg/mL (1 mL total volume), or 40 μg/2 mL.

4. METHODS OF STERILIZATION:
The drug product is filled.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the diagnosis and treatment of male erectile dysfunction.

B. 1. DATE OF INITIAL SUBMISSION: 26 July 1996

2. DATE OF AMENDMENT: 21 April 1997 (Subject of this review.)

3. RELATED DOCUMENTS:

| | |
|---|---|
| IND | IND |
| NDA 20-379 | NDA 18-484 |
| DMF | DMF |

4. ASSIGNED FOR REVIEW: 13 May 1997

C. REMARKS: The application is for a sterile, isotonic solution of alprostadil in polyethylene ampules. Each ampule will be packaged in an individual foil blister pack. For each dose of product a pouch containing one empty 2 mL plastic syringe, one individual packaged 27 gauge ½ inch needle and one alcohol swab will be supplied.

The product is to be stored frozen at the pharmacy and may be stored for one month under refrigeration after dispensing.

The product will be manufactured for the applicant by:

is responsible for the release of product for sale, control of the quality assurance program, and for GMP compliance.

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

2 June 1997

Paul Stinavage, Ph.D.

cc: Original NDA 20-755
HFD-580/T. Rumble
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 2 June 1997
R/D initialed by P. Cooney 6-5-97