CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-088

MICROBIOLOGY REVIEW(S)

NOV 23 1999

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-088
16 November 1999

A. 1. NDA 21-088 BI

APPLICANT: ALZA Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

2. PRODUCT NAMES: DUROS™ Leuprolide Implant

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an implant containing 65 mg of leuprolide.

4. METHODS OF STERILIZATION:
The product employs a combination of aseptic filling and terminal irradiation.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the palliative treatment of advanced prostate cancer.

B. 1. DATE OF INITIAL SUBMISSION: 30 April 1999

2. DATE OF AMENDMENT: 13 August 1999 (Subject of this Review)

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: 11 November 1999

C. REMARKS:
The manufacture of the product is performed at ALZA Corporation at the following campuses:

ALZA Corporation	ALZA Corporation	ALZA Corporation
950 Page Mill Road	1010 Joaquin Road	700 Eubanks Drive
Palo Alto, CA 94304	Mtn. View, CA 94043	Vacaville, CA 95688

The sterile implanter is supplied by:

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

/S/ 16 November 1999
Paul Stinavage, Ph.D.
Date 11/23/99

cc: Original NDA 21-088
HFD-580/Div. Files/J. Mercier
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 16 November 1999
R/D initialed by P. Cooney