CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-708

MICROBIOLOGY REVIEW(S)

Parks

JAN 24 1997

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW No. 1 OF NDA

22 January 1997

A. 1. NDA 20-708

SPONSOR TAP Pharmaceuticals
2355 Waukegan Rd.
Deerfield Illinois, 60015

2. PRODUCT NAMES: Lupron Depot®-3 Month 11.25 mg (leuprolide acetate for depot suspension)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Vials filled with lyophilized powder (dry fill process) and packaged with diluent solution. The suspension is for intramuscular injection.

4. METHOD(S) OF STERILIZATION: The lyophilized powder is aseptically processed. The solution for reconstitution is terminally sterilized.

5. PHARMACOLOGICAL CATEGORY: Synthetic gonadotropin secretion inhibitor

6. DRUG PRIORITY CLASSIFICATION: 3S

B. 1. DATE OF INITIAL SUBMISSION: 6 March 1996

2. DATE OF AMENDMENT: 1 May 1996

3. RELATED DOCUMENTS: NDA 20-517 Lupron Depot®-4 Month 30 mg (leuprolide acetate for depot suspension), and DMF

4. ASSIGNED FOR REVIEW: 20 May 1996

C. REMARKS: The applicant states that this process is the same as the process for manufacturing Lupron Depot®-4 Month 30 mg (NDA 20-517). That Supplement 001 to that NDA was reviewed and recommended for approval by Dr. Brenda Uratani (reviews dated 05/22/96 and 06/13/96).

D. CONCLUSIONS: No action is indicated by microbiology on this supplement and the submission may be approved for sterility assurance issues.

1-22-97

David Hussong, Ph.D.

PK 1/24/97

cc:

HFD 580/Consult File
HFD 580/CSO/L. Pauls
HFD 580/Rev Chemist
HFD 805/D. Hussong

Drafted by: D. Hussong, 01/22/97
R/D initialed by: P. Cooney

Filename, c:\d\nda\20-708.RV1