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**APPLICATION NUMBER:   NDA 20-708**

**MICROBIOLOGY REVIEW(S)**

PAUCS  
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

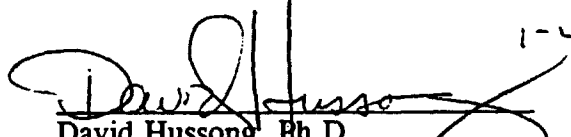
2. DATE OF AMENDMENT: 1 May 1996

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.

  
David Hussong, Ph.D.  
1-22-97  
JHC 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:\nda\20-708.RV1