Approval Package for:

APPLICATION NUMBER:
NDA 19-010/S-006

Name: Lupron Injection, leuprolide acetate (5mg/ml)

Sponsor: TAP Pharmaceuticals, Inc.

Approval Date: May 09, 1988
**APPLICATION NUMBER:**
NDA 19-010/S-006

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APPLICATION NUMBER:
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APPROVAL LETTER
NDA 19-010/5-006

TAP Pharmaceuticals
Attn: Dean P. Sandberg
Regulatory Affairs
1400 Sheridan Road
North Chicago, IL 60064

Dear Mr. Sandberg:

Reference is made to your supplemental new drug application dated December 24, 1987, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron (leuprolide acetate) Injection.

The supplemental application provides for a change in the bulk synthesis of leuprolide acetate.

We have completed our review of this supplemental application, and it is approved. We recommend that an "example of actual practice" (see Drug Substance Guidelines, page 13, paragraph 3) be submitted.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for approved NDAs.

Sincerely yours,

[Signature]

Soloman Sobel, M.D.
Director
Division of Metabolism and Endocrine Drug Products, HFD-510
Center for Drug Evaluation and Research

CC: NDA Arch.
HFD-510
HFD-510/HNunn/DKertesz
HFD-511/PVaccari 5/4/88/ft/ck/5/5/88 WANG 1502r 2 5 8

SUPPLEMENT APPROVAL
3. NAME AND ADDRESS OF APPLICANT (City and State)
   TAP Pharmaceuticals
   North Chicago, IL 60064

4. NAME OF DRUG
   Lupron

5. NONPROPRIETARY NAME
   Leuprolide acetate

9. PURPOSE OF SUPPLEMENT
   A revised synthesis of the drug substance

12. PHARMACOLOGICAL CATEGORY
   Antineoplastic

14. DOSAGE FORM
   Injection

15. HOW DISPENSED
   [ ] RX [ ] OTC

17. POTENCY (mg)
   5 mg/ml

19. CHEMICAL NAME
   CURRENT [ ] YES [ ] NO

21. CHEMICAL FORMULA
   -Leu-<7
   pGlu-His-Trp-Ser-Tyr-D-Leu-Arg-Pro-NHET
   1 2 3 4 5 6 YA B 9

23. CONCLUSIONS
   Information in support of the proposed changes is satisfactory. Issue approval letter.

APPROVED
Recommend submission of "example of actual practice" see Drug Subst. Guidelines
p.13, par. 3

DJK

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

R/D signed by D.J. Kenter 4/27/88