CENTER FOR DRUG EVALUATION AND RESEARCH

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-010/S-006

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EA/FONSI	
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NDA

19-010

S-006

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APPLICATION NUMBER:

NDA 19-010/S-006

APPROVAL LETTER

MAY 9 1988

NDA 19-010/S-006

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

Dear Mr. Sundberg:

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,

5/5/88

Solomon 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/ek/5/5/88 WANG 1502r
Concurrences: HNunn/DKertesz/5/4/88/ft/PLV/5/5/88

SUPPLEMENT APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-010/S-006

CHEMISTRY REVIEW(S)

APR 25 1988

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: HFD-510	2. NDA NUMBER: 19-010
3. NAME AND ADDRESS OF APPLICANT *(City and State)*: TAP Pharmaceuticals, North Chicago, IL 60064 APR 25 1988	4. DATE NDA APPROVED
	5. IF PRIOR TO OCT 10, 1962, DATE APPROVED FOR EFFICACY
6. NAME OF DRUG: Lupron	7. NONPROPRIETARY NAME: Leuprolide acetate
	8. SUPPLEMENT — NUMBER: S-006; DATE: 12/24/87
9. PURPOSE OF SUPPLEMENT: A revised synthesis of the drug substance	10. AMENDMENT DATE(s)
	11. OTHER DATE *(Report, etc.)*
12. PHARMACOLOGICAL CATEGORY: Antineoplastic	13. AF NUMBER
	16. RELATED IND/NDA/MF(s)
14. DOSAGE FORM: Injection	15. HOW DISPENSED: [X] Rx [ ] OTC
17. POTENCY(ies): 5 mg/ml	18. DRUG REQUIRES: [ ] NDA [ ] ANDA
19. CHEMICAL NAME	20. RECORDS AND REPORTS — CURRENT: [X] YES [ ] NO; REVIEWED: [X] YES [ ] NO

21. CHEMICAL FORMULA

-Leu-
pGlu-His-Trp-Ser-Tyr-D-Leu-Arg-Pro-NHET
1 2 3 4 5 6 7 8 9

22. REMARKS

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

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. Guidlines p.13, par. 3 DJK

24. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
H.B. Nunn	H. B. Nunn	4/25/88

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D. Kertesz 4/27/88