

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-010/S-024

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

Sponsor: TAP Pharmaceuticals, Inc.

Approval Date: May 16, 2002

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APPLICATION NUMBER:

NDA 19-010/S-024

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APPLICATION NUMBER:

NDA 19-010/S-024

APPROVAL LETTER



NDA 19-010/S-023, S-024

TAP Pharmaceutical Products, Inc.
Attention: John Lieberman, Ph.D.
Principle Regulatory Advisor
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lieberman:

Please refer to your supplemental new drug applications dated October 8, 2001, received October 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron® (leuprolide acetate) Injection.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for an alternate site for pyrogen testing of the finished drug product.

We have completed the review of these supplemental applications, and they are approved.

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

If you have any questions, call Leslie Stephens, MSN, RN, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

David Lin, Ph.D.
Chemistry Team Leader, DNDC II for the
Division of Reproductive and Urologic Drug Products,
(HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

David T. Lin
5/16/02 03:47:28 PM
I concur.

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APPLICATION NUMBER:

NDA 19-010/S-024

CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF Supplement

1. ORGANIZATION: HFD 580
2. NDA NUMBER: 19010
3. SUPPLEMENT NUMBERS/DATES: SCM024
Letterdate: 08-OCT-2001
Stampdate: 09-OCT-2001
4. AMENDMENTS/REPORTS/DATES:
Letterdate:
Stampdate:
5. RECEIVED BY CHEMIST: 14-OCT-2001

6. APPLICANT NAME AND ADDRESS: TAP Pharmaceutical Product Inc.
675 N. Field Drive
Lake Forest, IL 60045

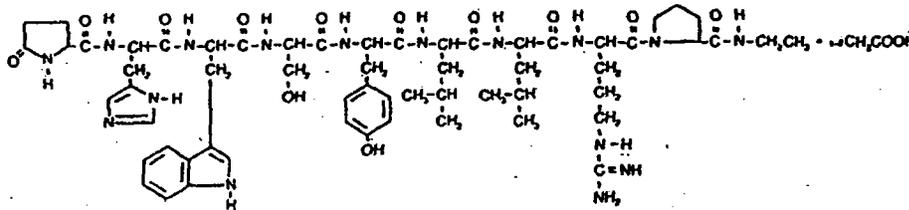
7. NAME OF DRUG: Lupron®

8. NONPROPRIETARY NAME: Leuprolide Acetate Injection

9. CHEMICAL NAME/STRUCTURE:

Chemical name: 5-Oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-Tyrosyl-D-leucyl-L-leucyl-L-arginyl-N-ethyl-L-Prolinamide acetate.

Structural Formula:



10. DOSAGE FORM(S): Sterile Solution for Injection

11. POTENCY: 1 mg/0.2 ml

12. PHARMACOLOGICAL CATEGORY: Palliative treatment of advanced prostatic cancer

13. HOW DISPENSED: Subcutaneous Injection

14. RECORDS & REPORTS CURRENT: Yes

15. RELATED IND/NDA/DMF: None

16. "Supplement-Changes Being Effected in 30 days" Provides for
An Alternate site for pyrogen testing of the finished drug product.

17. **COMMENTS:** This is a CBE-supplement-provided to request an approval of an alternate site for pyrogen testing of the finished drug product. The address of the proposed facility is:

[]

The sponsor commits that the alternate facility [] will use only the test methods approved in the application or methods that have been implemented under 21 CFR 314.70 (d). The sponsor has included [] GLP and debarment certifications and statement concerning the closeout of its last FDA inspectional observations. A request has been forwarded through EES on 12-December-2001. Overall recommendation was found acceptable on 18-March-2002 by J.D.Ambrogio (HFD-324) 301-827-0062 (see attached EES recommendation report).

18. CONCLUSIONS AND RECOMMENDATIONS:

Based on the information provided by the firm and the EES recommendation, this supplement may be approved.

Issue an "approval" letter

19. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Swapan K. De, Ph.D.		04/25/2002

cc:

Orig. NDA #19-010
HFD-580/Division File
HFD-580/
HFD-580/DTLin/SDe
R/D Init by: DTLin, Ph.D.

filename: nda19010.scm024

Application: NDA 19010/024 Action Goal:
Stamp: 09-OCT-2001 District Goal: 05-MAR-2002
Regulatory Due: 09-APR-2002 Brand Name: LUPRON
Applicant: TAP PHARM Estab. Name:
675 NORTH FIELD DR Generic Name: LEUPROLIDE ACETATE
LAKE FOREST, IL 60045
Priority: 1P Dosage Form: (INJECTION)
Org Code: 580 Strength: 5MG/ML

Application Comment: THIS SUPPLEMENT-CHANGES BEING EFFECTED IN 30 DAYS REQUESTS APPROVAL OF AN ALTERNATE SITE FOR PYROGEN TESTING OF THE FINISHED DRUG PRODUCT. (on 12-DEC-2001 by S. DE ())

FDA Contacts: J. BEST (HFD-410) 301-827-3234 , Project Manager
S. DE , Review Chemist
D. LIN (HFD-580) 301-827-4230 , Team Leader

Overall Recommendation: ACCEPTABLE on 18-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: []

DMF No:

AADA: []

Responsibilities: []

Profile: CTL

OAI Status: NONE

Estab. Comment: THE ADDRESS OF THE ALTERNATE SITE PROPOSED IS []
[] THE SUBMISSION CONTAIN [] GLP
AND DEBARMENT CERTIFICATIONS AND FDA INSPECTION CLOSEOUT. (on 12-DEC-2001 by S. DE ())

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	12-DEC-2001				DES
SUBMITTED TO DO	13-DEC-2001	GMP			FERGUSONS
ASSIGNED INSPECTION	13-DEC-2001	PS			CEVERLY
INSPECTION SCHEDULED	14-DEC-2001		08-FEB-2002		CEVERLY
INSPECTION PERFORMED	27-FEB-2002		01-FEB-2002		CEVERLY
DO RECOMMENDATION	18-MAR-2002			ACCEPTABLE INSPECTION	CEVERLY

A PRE-APPROVAL AND GMP INSPECTION OF THIS CONTRACT TEST LAB WAS CONDUCTED 1/28/02-2/1/02.



CARYN EVERLY, PRE-APPROVAL MANAGER
LOS ANGELES DISTRICT.

OC RECOMMENDATION 18-MAR-2002

ACCEPTABLE DAMBROGIOJ
DISTRICT RECOMMENDATION

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/s/

Swapn De
4/25/02 02:46:38 PM
CHEMIST

David T. Lin
4/25/02 02:56:56 PM
CHEMIST
I concur.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-010/S-024

CORRESPONDENCE



NDA 19-010/S-024

CBE-30 SUPPLEMENT

TAP Pharmaceutical Products, Inc.
Attention: John R. Lieberman, Ph.D.
Principal Regulatory Advisor
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lieberman:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Lupron® (leuprolide acetate) Injection

NDA Number: 19-010

Supplement Number: S-024

Date of Supplement: October 8, 2001

Date of Receipt: October 9, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes the following change: provides for an alternate site for pyrogen testing of the finished drug product.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on December 8, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be April 9, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

NDA 19-010/S-024

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If you have any questions, call me at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Jeanine Best, M.S.N., R.N.
Senior Regulatory Associate
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Jeanine Best

10/10/01 01:18:47 PM