CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 19-732/S-007

Name:	Lupron Depot leuprolide acetate (7.5 mg)
Sponsor:	TAP Pharmaceuticals, Inc.
Approval Date:	January 26, 1989

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APPLICATION NUMBER:

NDA 19-732/S-007

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APPLICATION NUMBER:

NDA 19-732/S-007

APPROVAL LETTER

NDA 19-732/S-007
NDA 20-011/S-003
NDA 20-263/S-003

FEB 14 1994

TAP Pharmaceuticals, Inc.
Attention: S. Albert Edwards, Pharm.D.
Regulatory Products Manager
2355 Waukegan Road
Deerfield, IL 60015

Dear Dr. Edwards:

Please refer to your supplemental new drug applications dated December 10, 1993, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Lupron Depot (leuprolide acetate for depot suspension), 7.5 mg (NDA 19-732);

Lupron Depot (leuprolide acetate for depot suspension), 3.75 mg (NDA 20-011); and

Lupron Depot PED (leuprolide acetate for depot suspension), (NDA 20-263).

The supplemental applications provide for extension of the expiration period for the PGLA solution from four weeks to eight weeks at below 10°C.

We have completed the review of these supplemental applications and they are approved, effective on the date of this letter.

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

Sincerely yours,

/S/ 2/14/94

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

cc:
Original NDA
HFC-130/JAllen
HFD-510
HFD-510/CNiu/YYChiu
HFD-80
HFD-511/LBraithwaite/01.31.94/N20011AP.S03
Concurrences: Niu/Chiu 2.1.94

APPROVAL

LB 2/14/94

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APPLICATION NUMBER:

NDA 19-732/S-007

CHEMISTRY REVIEW(S)

ORIGINAL JAN 26 1994

CHEMIST'S REVIEW	1. ORGANIZATION DMEDP, HFD-510	2. NDA NUMBER 19-732
3. NAME AND ADDRESS OF APPLICANT TAP Pharmaceuticals Inc. Department T85/J15 2355 Waukegan Road Deerfield, IL 60015		4. SUPPLEMENT NUMBER, DATE Supplement S-007 12/10/93
5. NAME OF THE DRUG Lupron Depot	6. NONPROPERIETARY NAME Leuprolide acetate for depot suspension	8. AMENDMENTS/ REPORTS, DATE
7. SUPPLEMENT PROVIDES FOR: Extension of the expiration period for the PLGA solution from four weeks to eight weeks at below 10°C		
9. PHARMACOLOGICAL CATEGORY GnRH agonist	10. HOW DISPENSED RX	RELATED IND/NDA/DMF NDA #20-011 NDA #20-263
12. DOSAGE FORM Microsphere powder	13. POTENCY 7.5 mg	

14. CHEMICAL NAME AND STRUCTURE
See Chem. Rev. # 1

15. COMMENTS
See next page.

16. CONCLUSIONS AND RECOMMENDATIONS
The submitted data support the extension of the expiration period from four weeks to eight weeks when the PLGA solution is stored below 10°C. Issue an approval letter.

17. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Chien-Hua Niu, Ph.D.		1/26/94

DISTRIBUTION: ORIGINAL JACKET REVIEWER DIVISION FILE

R/D initialed by:
Disc Supplement #2: NDA19732.S07 1/26/94

Redacted 1 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review
(S-007)

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APPLICATION NUMBER:

NDA 19-732/S-007

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date DEC 20 1993

NDA No. 19-732

Tap Pharmaceuticals Inc.
Dept. TB5/J15
2355 Waukegan Road
Deerfield, IL 60015

Attention: Aruna Dabholkar, M.D.

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Lupron Leuprolide acetate

NDA Number: 19-732

Supplement Number: S-007

Date of Supplement: December 10, 1993

Date of Receipt: December 13, 1993

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control Room 14B-03
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours,

Supervisory Consumer Safety Officer
Division of Metabolism and Endocrine Drug Products
Center for Drug Evaluation and Research

FORM FDA 3217c (3/93)

TAP PHARMACEUTICALS INC.

ORIGINAL

NDA NO. 19232 REF. NO. 007

NDA SUPPL FOR SCE

Noted
Review completed
Labeling Rev. for
S-007) Chi 1/27/94

Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, Illinois 60015

December 10, 1993

CENTER FOR DRUG
REC'D
DEC 13 1993
HFD-510
EVALUATION AND RESEARCH

Division of Metabolism and Endocrine Drug Products, HFD-510
Document Control Room 14B-03
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Lupron Depot 7.5 mg (leuprolide acetate for depot suspension)
Supplement
NDA 19-732

Dear Dr. Sobel:

Pursuant to 21 CFR 314.70(c), submitted for your review and approval is a supplement to extend the expiration period for PLGA Solution used in the manufacturing process of Lupron Depot.

The stability data for PLGA solution is attached with a summary and FDA Form 356h. We request to extend the expiration period from four weeks to eight weeks at below 10° C.

Sincerely,

Aruna Dabholkar, M.D.
Regulatory Products Manager
(708) 317-4893

AD/pjp
Attachment

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☒ N.A.I.
CSO INITIALS DATE

aruna/dec8d

DATED 2/14/94

CB 2/15/94