CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 19-943/S-003

Name:	Lupron Depot 3.75 mg leuprolide acetate
Sponsor:	TAP Pharmaceuticals, Inc.
Approval Date:	October 26, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-943/S-003

CONTENTS

Reviews / Information Included in this Review	
Approval Letter	X
Approvable Letter(s)	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Administrative Document(s)	
Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-943/S-003

APPROVAL LETTER

TYPOGRAPHICAL ERROR

Approval Letter (10/25/95)-
NDA 19-943/S-002 is a typographical error. Should state NDA 19-943/S-003.

4-1

NDA 19-732/S-009
NDA 19-943/S-002
NDA 20-011/S-006
NDA 20-263/S-006

OCT 26 1995

TAP Holdings Inc.
Attention: Aruna Dabholkar, M.D.
2355 Waukegan Road
Deerfield, IL 60015

Dear Dr. Dabholkar:

Please refer to your December 30, 1994, supplemental new drug applications 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 19-943);
Lupron Depot (leuprolide acetate for depot suspension), 3.75 mg (NDA 20-011); and
Lupron Depot (leuprolide acetate for depot suspension), 7.5, 11.25, and 15.0 mg (NDA 20-263).

We acknowledge receipt of your amendments dated May 24, September 1 (NDA 19-732) and September 7 (NDAs 19-943, 20-011, and 20-263), 1995.

These supplemental applications provide for an additional container/closure system (pre-filled, dual-chamber syringe) filled with Lupron Depot and diluent.

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.

If you have any questions, please contact:

Lana L. Pauls, M.P.H.
Consumer Safety Officer
(301) 443-3510

Sincerely yours,

10/26/95

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

cc:
Original NDAs 19-943, 19-732, 20-011, and 20-263
HFD-510
HFD-510/CNiu/YYChiu
HFD-80
DISTRICT OFFICE
HFD-232

drafted: LPauls/October 23, 1995/N19732AP.S09

Concurrences:
CNiu, SMoore 10.23.95

APPROVAL

LP 10/25/95

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-943/S-003

CHEMISTRY REVIEW(S)

TYPOGRAPHICAL ERROR

Chemistry Review (10/19/95)-
SCP-002 is a typographical error. Should state SCP-003.

OCT 19 1995

CHEMIST'S REVIEW	1. ORGANIZATION DMEDP, HFD-510	2. NDA NUMBER 19-943
3. NAME AND ADDRESS OF APPLICANT TAP Pharmaceuticals Inc. Bannockburn Lake Office Plaza 2355 Waukegan Road Deerfield, IL 60015		4. SUPPLEMENT NUMBER, DATE Supplement SCP-002 12/30/94
5. NAME OF THE DRUG Lupron Depot, 3.75 mg	6. NONPROPRIETARY NAME Leuprolide acetate for depot suspension	8. AMENDMENTS/ REPORTS, DATE Amendment 5/24/95 9/7/95
7. SUPPLEMENT PROVIDES FOR: Additional container-closure system (Pre-filled, Dual Chamber Syringe) filled with Lupron Depot and diluent.		
9. PHARMACOLOGICAL CATEGORY Inhibitor of gonadotropin secretion	10. HOW DISPENSED RX	RELATED IND/NDA/DMF DMF [ ] DMF [ ]
12. DOSAGE FORM Microsphere Depot	13. POTENCY 3.75 mg	NDA #19-732/S09 NDA #20-011/S06 NDA #20-263/S06

14. CHEMICAL NAME AND STRUCTURE

5-Oxo-L-prolyl-L-histidyl-L-Tryptophyl-L-seryl-L-Tyrosyl-D-leucyl-L-leucyl-L-arginyl-N-ethyl-L-prolinamide acetate

15. COMMENTS

1. The complete response to chemistry deficiencies communicated to the applicant in the non-approval letter dated April 25, 1995 is submitted to the 5/24/95 amendment to Supplement SCP-006 of NDA #19-732.

2. For other comments, see Chem. Rev. #2 for S-009 to NDA 19-732.

16. CONCLUSIONS AND RECOMMENDATIONS

The sponsor has properly responded the deficiencies in chemistry and the cGMP inspection was acceptable to the Office of Compliance. Moreover, the sterilization validation process has been reviewed by the microbiologist and found to be satisfactory (see microbiologist's review #3 dated 10/4/95). The application can be approved from chemistry viewpoint. Issue an approval letter. In the approval letter, the microbiologist's comments should be communicated to the firm.

17. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Chien-Hua Niu, Ph.D.	Chien-Hua Niu	10/19/95

DISTRIBUTION: ORIGINAL JACKET REVIEWER DIVISION FILE

R/D initialed by:

Disc Supplement #3/NDA19943.S2A

Stephen Moore 10/19/95

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-943/S-003

CORRESPONDENCE

ORIGINAL
SS-003
BC

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

Lakeside Office Plaza
2355 Waukegan Rd.
Deerfield, IL 60015

Dated
Revised/updated
Late class. Rec. for Sep-002

10/19/95

September 7, 1995

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

RE: Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension)
NDA 19-943/S-003 (Prefilled Dual Chamber Syringe)
Amendment No. 002 (Response to Deficiency Letter)

Dear Doctor Sobel:

Pursuant to 21 CFR 314.120(a)(1) we are amending the SNDA 003 for Prefilled Dual Chamber Syringe (additional container/closure system).

The complete response to the deficiency letter dated August 10, 1995, is submitted to NDA 19-732 (SNDA 009, Amendment No. 002).

Attached is the FDA Form 356h with request to cross refer.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date APR 20 1995

NDA No. 19-943

Tap Holdings Inc.
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 Depot

NDA Number: 19-943

Supplement Number: S-003

Date of Supplement: April 14, 1995

Date of Receipt: April 17, 1995

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,

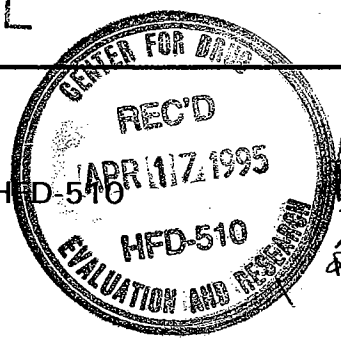
Supervisory Consumer Safety Officer
Division of Metabolism and Endocrine Drug Products
Center for Drug Evaluation and Research

NDA SUPPLEMENT NDA SUPPL ~~AMEND~~

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

ORIGINAL



HB 2-13-96 Reviewed

April 14, 1995

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

NDA NO. 19943 REF. NO. 003

NDA SUPPL FOR 9C9

RE: Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension)
NDA 19-943
Supplemental Application for Prior Approval

Dear Doctor Sobel:

The sponsor, TAP Holdings Inc., submits this Supplemental Application under the provisions of Section 505(i) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.70 (b) (2) (vi) and (vii).

This supplement requests for approval of an additional container closure system for Lupron Depot 3.75 mg approved under NDA and 19-943 on March 30, 1995.

All the information required for this supplemental application is submitted under our NDA 19-732 (Lupron Depot® 7.5 mg) in the supplement No. 009 dated December 30, 1994. Four copies of revised draft labeling and package labels are enclosed along with FDA Form 356h and the request to cross refer.

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

Reviewed 10/25/00