CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 19-732/S-009

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-732/S-009

CONTENTS

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-732/S-009

APPROVAL LETTER

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,

10/23/95

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

10/25/95

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-732/S-009

CHEMISTRY REVIEW(S)

APR 1 2 1995

ORIGINAL

CHEMIST'S REVIEW	1. ORGANIZATION DMEDP, HFD-510	2. NDA NUMBER 19,732

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-009
12/30/94

5. NAME OF THE DRUG

Lupron Depot, 7.5 mg

6. NONPROPRIETARY NAME

Leuprolide acetate for depot suspension

8. AMENDMENTS/REPORTS, DATE

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 [ ]
NDA 20-011/S06
NDA 20-263/S06

12. DOSAGE FORM

Microsphere Depot

13. POTENCY

7.5 mg

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 syringe components [ ] are purchased from [ ]. An authorization letter issued by [ ] permitting the FDA to cross reference its DMF [ ] on behalf of the sponsor is included.

16. CONCLUSIONS AND RECOMMENDATIONS

The supplement is not approvable due to the deficiencies in chemistry and in the sterilization process validation. Also, the cGMP inspection has not been completed. Issue a non-approval letter (see the draft letters in this review and microbiology review). (2)

17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Chien-Hua Niu, Ph.D.		4/12/95

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R/D initialed by:

Disc Supplement/NDA19732.S09

4/12/95

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information from

Chemistry Review #1
(S-009)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE (Check One)	DATE	PHONE NO.	CERI ID
Original ☐ Follow-Up ☐ FUR	2/1/95	443-3520	

REQUESTOR'S NAME	DIVISION	MAIL CODE
Chien-Hua Niu	DMEDP	HFD- 510

APPLICATION AND SUPPLEMENT NUMBER
NDA #19-732 (SCP-009)

BRAND NAME	ESTABLISHED NAME
Lupron Depot	Leuprolide acetate for depot suspension

DOSAGE AND STRENGTH	STERILE
Microsphere powder, 7.5 mg	☒ YES ☐ NO

PROFILE CLASS	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)
~~SVP~~ SVS	

APPLICANT'S NAME
TAP Pharmaceuticals Inc.

ADDRESS
Bannockburn Lake Office Plaza, 2355 Waukegan Rd., Deerfield, IL 60015

COMMENTS
1. Identical requests are made for NDA #20-011 (SCP-006) and NDA #20-263 (SCP-006).

2. The field copy of this submission is kept in my office.

User Fee date 7/3/95

FACILITIES TO BE EVALUATED
(Name and Complete Address)

		RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	F KEY/ CIRTS ID	HFD-324 USE ONLY
1.	[redacted]	[redacted]	Type III DMF [redacted] SVS	[redacted]	CA 7/19/95 See attached
2.					
3.	Takeda Chemical Industries, Ltd. Osaka Plant (C-71 Building) 17-85 Juso-Honmachi 2-Chome Yodogawa-Ku Osaka, 532, Japan	Manufacturing Pre-filled Dual-Chamber Syringes filled with diluent and microsphere powder.	SVS	[redacted] TAKO	AC 7/5/95
4.				[redacted]	
5.	Abbott Laboratoires 1400 Sheridan Road North Chicago, IL 60064	Labeling and packaging	SVS	[redacted] ABLN	AC 7/13/95

FOR HFD-324 USE ONLY	CSO	DATE RECEIVED
	Nicholas Fleischer	7/3/95
	CGMP COMPLIANCE STATUS	DATE
	Acceptable	8/14/95

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324. Remaining Copies: Requesting Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE (Check One)	DATE	PHONE NO.	[redacted]
☒ Original ☐ Follow-Up ☐ FUR	2/1/95	443-3520	

REQUESTOR'S NAME	DIVISION	MAIL CODE
Chien-Hua Niu	DMEDP	HFD- 510

APPLICATION AND SUPPLEMENT NUMBER
NDA #19-732 (SCP-009)

BRAND NAME	ESTABLISHED NAME
Lupron Depot	Leuprolide acetate for depot suspension

DOSAGE AND STRENGTH	STERILE
Microsphere powder, 7.5 mg	☒ YES ☐ NO

PROFILE CLASS	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)
SVP	

APPLICANT'S NAME
TAP Pharmaceuticals Inc.

ADDRESS
Bannockburn Lake Office Plaza, 2355 Waukegan Rd., Deerfield, IL 60015

COMMENTS
1. Identical requests are made for NDA #20-011 (SCP-006) and NDA #20-263 (SCP-006).

2. The filed copy of this submission is kept in my office.

FACILITIES TO BE EVALUATED
(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	F KEY/ CIRTS ID	HFD-324 USE ONLY
1. [redacted]	[redacted]	Type III DMF [ ]		
2.				
3. Takeda Chemical Industries, Ltd. Osaka Plant (C-71 Building) 17-85 Juso-Honmachi 2-Chome Yodogawa-Ku Osaka, 532, Japan	Manufacturing Pre-filled Dual-Chamber Syringes filled with diluent and microsphere powder.			
4.				
5. Abbott Laboratoires 1400 Sheridan Road North Chicago, IL 60064	Labeling and packaging			

FOR HFD-324 USE ONLY	CSO	DATE RECEIVED
	CGMP COMPLIANCE STATUS	DATE

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324. Remaining Copies: Requesting Office

TYPOGRAPHICAL ERROR

Chemistry Review #2 (10/19/95)-
"Microbiologist's Review #3" under item 16. Conclusions and Recommendations is a typographical error. Should state Microbiologist's Review #2.

ORIGINAL OCT 18 1995

CHEMIST'S REVIEW	1. ORGANIZATION DMEDP, HFD-510	2. NDA NUMBER 19,732
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-009 12/30/94
5. NAME OF THE DRUG Lupron Depot, 7.5 mg	6. NONPROPRIETARY NAME Leuprolide acetate for depot suspension	8. AMENDMENTS/ REPORTS, DATE Amendment 5/24/95 9/1/95
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 [ ] NDA 19-943/S02 NDA 20-011/S06 NDA 20-263/S06
12. DOSAGE FORM Microsphere Depot	13. POTENCY 7.5 mg	

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 5/24/95 amendment to NDA #19-732 (Supplement SCP-009) is in response to chemistry deficiencies communicated to the applicant in the non-approval letter dated on April 25, 1995.

2. For other comments, see the next page.

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

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R/D initialed by:

Disc Supplement/NDA19732.S9A

Stephen Moore 10/19/95

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information from

Chemistry Review #2
(S-009)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-732/S-009

MICROBIOLOGY REVIEW(S)

ORIGINAL

MAR 17 1995

Consultative Review to HFD-510
DIVISION OF MEDICAL IMAGING, SURGICAL,
and DENTAL DRUG PRODUCTS; HFD-160

Microbiologist's Review of Supplement
17 March 1995

A. 1. NDA 19-732/S-009
APPLICANT: TAP Pharmaceuticals, Inc.
Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

2. PRODUCT NAMES: Lupron Depot® 7.5 mg, 3.75 mg, and Lupron Depot-PED® 7.5 mg, 11.25 mg, and 15 mg formulations (leuprolide acetate for depot suspension) for Injection.

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Sterile depot suspension for intramuscular injection. The Supplement provides for packaging the product in a dual-chambered syringe.

4. METHODS OF STERILIZATION:

[redacted]

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The drug product is used for palliative treatment of advanced prostate cancer.

B. 1. DATE OF INITIAL SUBMISSION: 30 December 1994

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS:

Appears This Way
On Original

Table 1. Documents referenced in this Supplement.

Document	Subject
NDA 19-010	Manufacture of Lupron Injection
NDA 19-732	Manufacture of Lupron Depot® 7.5 mg
NDA 20-011	Manufacture of Lupron Depot® 3.75 mg
NDA 20-263	Manufacture of Lupron Depot-PED® 7.5 mg, 11.25 mg, and 15 mg
DMF [ ]	[ ]
DMF [ ] (Type I) DMF [ ] (Type III)	[ ]

4. ASSIGNED FOR REVIEW: 6 February 1995

C. REMARKS: The supplement requests an additional container/closure system (prefilled, dual-chamber syringe) for Lupron Depot® 7.5 mg, 3.75 mg, and Lupron Depot-PED® 7.5 mg, 11.25 mg, and 15 mg formulations. The application also describes the manufacture of the diluent at Takeda's C-71 (Osaka) site. Unlabelled, pre-filled syringes will be shipped to Abbott Laboratories for labelling and packaging and will be distributed by TAP Pharmaceuticals.

D. CONCLUSIONS: The application is not recommended for approval. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of Letter to Applicant".

17 March 1995
Paul Stinavage, Ph.D.

cc: Original NDA 19-732
HFD-160/Stinavage/Consult File
HFD-510/Div File/L. Pauls
Drafted by: P. Stinavage
R/D initialed by P. Cooney

PAC 3/17/95

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information from

Microbiology Review #1
(S-009)

TYPOGRAPHICAL ERROR

Microbiology Review #2 (10/04/95)-
Title, "Microbiologist's Review #3" is a typographical error. Should state Microbiologist's Review #2.

Consultative Review to HFD-510
DIVISION OF MEDICAL IMAGING, SURGICAL,
and DENTAL DRUG PRODUCTS; HFD-160

ORIGINAL

Microbiologist's Review #3
4 October 1995

A. 1. NDA 19-732/S-009
APPLICANT: TAP Pharmaceuticals, Inc.
Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

2. PRODUCT NAMES: Lupron Depot® 7.5 mg (leuprolide acetate for depot suspension) for Injection.

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Sterile depot suspension for intramuscular injection. The Supplement provides for packaging the product in a dual-chambered syringe.

4. METHODS OF STERILIZATION:

[redacted]

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
Lupron® Depot 7.5 mg is used for palliative treatment of advanced prostate cancer.

B. 1. DATE OF INITIAL SUBMISSION: 30 December 1994

2. DATE OF AMENDMENT: 1 September 1995

Appears This Way
On Original

3. RELATED DOCUMENTS:

Document	Subject
NDA 19-010	Manufacture of Lupron Injection
NDA 19-732	Manufacture of Lupron Depot® 7.5 mg
NDA 20-011	Manufacture of Lupron Depot® 3.75 mg
NDA 20-263	Manufacture of Lupron Depot-PED® 7.5 mg, 11.25 mg, and 15 mg
DMF [ ]	[ ]
DMF [ ] (Type I) DMF [ ] (Type III)	[ ]

Table 1. Documents referenced in the Supplement.

4. ASSIGNED FOR REVIEW: 22 September 1995

C. REMARKS: The amendment is a response to deficiencies found in the 30 June 1995 review of the Supplemental New Drug Application.

D. CONCLUSIONS: The application is recommended for approval. The applicant should be reminded of their commitment to provide information post-approval. See "Draft Letter".

4 October 1995

Paul Stinavage, Ph.D.

PAC 10/4/95

cc: Original NDA 19-732
HFD-160/Stinavage/Consult File
HFD-510/Div File/L. Pauls
Drafted by: P. Stinavage, 4 October 1995
R/D initialed by P. Cooney, 4 October 1995

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information from

Microbiology Review #2
(S-009)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-732/S-009

CORRESPONDENCE

ORIGINAL

BC

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

Lannockburn Lake Office Plaza
2355 Waukegan Rd.
Deerfield, IL 60015

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
SEP 0 5 1995
HFD-510

September 1, 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

Noted
Review completed
(see chem. rev. for
SEP-009)
CMS
10/19/95

RE: Lupron Depot® 7.5 mg (leuprolide acetate for depot suspension)
NDA 19-732/S-009 (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 009 for Prefilled Dual Chamber Syringe (additional container/closure system).

Submitted herewith is the complete response to the deficiency letter dated August 10, 1995.

Attached is the information required to complete this amendment.

Sincerely,

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

AD/pjp
Attachment

REVIEWS COMPLETED

CSO ACTION:

☑ LETTER ☐ N.A.L.

CSO INITIALS 10/25/95 DATE

NDA SUPPL AMEND

ORIGINAL

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

SCP-009 AC

Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

NDA SUPPLEMENT

May 24, 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

CENTER FOR DRUG EVALUATION AND RESEARCH
MAY 25 1995
REC'D
HFD-510

RE: Lupron Depot® 7.5 mg (leuprolide acetate for depot suspension)
NDA 19-732/S-009 (Prefilled Dual Chamber Syringe)
Amendment No. 001 (Response to Deficiency Letter)

Noted
Review Completed
(See chem. rev. for SCP-009)
Elli
10/19/95

Dear Doctor Sobel:

Pursuant to 21 CFR 314.120 (a) (1) and as notified in our letter dated May 1, 1995, we are amending the SNDA 009 for Prefilled Dual Chamber Syringe (additional container/closure system).

Submitted herewith is the complete response to the non-approvable letter dated April 25, 1995.

Some of the additional information requested from [ ], the holder of DMF [ ], required response from Takeda which is also included in this amendment.

Please note that [ ] has submitted a response to update DMF [ ].

A desk copy of this submission has been sent to Dr. Niu.

Attached is all the information to complete this amendment.

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 10/25/95

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

APR 25 1995

Tap Holdings, Inc.
Attention: Aruna Dabholkar, M.D.
Regulatory Products Manager
2355Waukegan 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 20-011); and
Lupron® Depot PED (leuprolide acetate for depot suspension), (NDA 20-263).

We have completed our review and find the information presented is inadequate, and the supplemental applications are not approvable under section 505(d) of the Act and 21 CFR 314.125(b). The deficiencies may be summarized as follows:

Manufacturing/Quality Control:

1.

2.

3.

4.

Microbiology:

1.

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information from

Correspondence (Non-Approvable Letter - 4/25/95)
(S-009)

Please note, additional information has been requested from the [ ], the holder of DMF [ ]. A complete response must be submitted before the review clock can be activated.

Furthermore, these supplemental applications cannot be approved until we receive notification that the establishment is within cGMP compliance.

Within 10 days after the date of this letter, you are required to amend the supplemental applications, notify us of your intent to file amendments, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may proceed to withdraw these supplemental applications. Any amendments should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

If you have any questions, please contact:

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

Sincerely yours,

4/25/95

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 19-732, 20-011, 20-263
HFD-510
DISTRICT OFFICE
HFD-80
HFD-160/PStinavich/PCooney
HFD-510/CNiu/YYChiu
HFD-510/L.L.Pauls

drafted: LPauls/April 20, 1995/N19732NA.S09

Concurrences:
CNiu, YYChiu 04.24.95

NOT APPROVABLE (NA)

4/03/95

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date JAN 18 1995

NDA No. 19-732

TAP Pharmaceuticals, 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 7.5mg

NDA Number: 19-732

Supplement Number: S-009

Date of Supplement: December 30, 1994

Date of Receipt: January 03, 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,

EM Gallies

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

TAP PHARMACEUTICALS INC.

NDA NO. 19732 REF. NO. 009

NDA SUPPL FOR SCP (w/ Draft Labeling)

Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, Illinois 60015

December 30, 1994

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

ORIGINAL

RE: Lupron Depot® 7.5 mg (leuprolide acetate for depot suspension)
NDA 19-732
Supplemental Application for Prior Approval

Dear Doctor Sobel:

The sponsor, TAP Pharmaceuticals 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 7.5 mg approved under NDA 19-732.

This supplement consists of 3 volumes labeled as Volume 1.1 - 1.3. The volume 1.1 contains all chemistry, manufacturing and controls information. Volume 1.2 contains information on facilities and [ ] process validations for review by CDER's Sterile Products Group. This volume is labeled as "Sterile Process Validation Package." Three copies of each Volume 1.1 and 1.2 are submitted. Four copies of the Methods Validation Package (Volume 1.3) are submitted and are labeled appropriately.

Attached is the information required for this supplement.

Sincerely,

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

AD/pjp
Attachment

REVIEWS COMPLETED
CSO ACTION: ☑ LETTER ☐ N.A.I.
LLP

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JAN 03 1995
HFD-510

CN — Do you need a consult to micro?
LLP 1/9/95

all samples accepted 4-28-98