

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-263/S-006

Name: Lupron Depot-PED
7.5 mg, 11.25 mg, 15 mg
(leuprolide acetate for depot suspension)
&
Lupron Injection
(leuprolide acetate)

Sponsor: TAP Pharmaceuticals, Inc.

Approval Date: October 26, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:
NDA 20-263/S-006**

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-263/S-006

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.

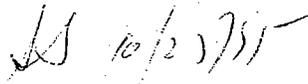
We have completed the review of these supplemental applications and they are approved, effective on the date of this letter.

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,


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

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

Page 2

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

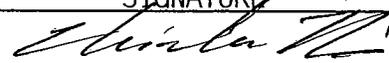
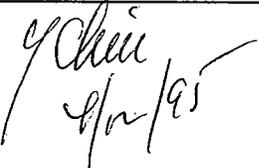
APPLICATION NUMBER:

NDA 20-263/S-006

CHEMISTRY REVIEW(S)

APR 12 1995

ORIGINAL

CHEMIST'S REVIEW		1. ORGANIZATION DMEDP, HFD-510	2. NDA NUMBER 20-263
3. NAME AND ADDRESS OF APPLICANT TAP Pharmaceuticals Inc. Bannockburn Lake Office Plaza 2355 Waukegan Road Deerfield, IL 60015		4. SUPPLEMENT NUMBER, DATE Supplement S-006 12/30/94	
5. NAME OF THE DRUG Lupron Depot PED	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 <input type="checkbox"/> <input checked="" type="checkbox"/> DMF <input type="checkbox"/> <input checked="" type="checkbox"/> NDA 10-732/S09 NDA 20-011/S06
12. DOSAGE FORM Microsphere Depot	13. POTENCY 7.5 mg, 11.25 mg and 15.0 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 <input type="checkbox"/> are purchased from <input type="checkbox"/> . Pre-filled dual chamber syringes <input type="checkbox"/> are manufactured by Takeda. <input checked="" type="checkbox"/>			
2. For other comments, see Chem. Rev. for S-009 to NDA 19-732.			
3. With respect to chemistry, manufacturing and controls for pre-filled dual chamber syringes, see Chem. Rev. for S-009 to NDA 19-732.			
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 for Supplement S-009 to NDA #19-732). (9)			
17. NAME Chien-Hua Niu, Ph.D.		REVIEWER SIGNATURE 	DATE COMPLETED 4/12/95
DISTRIBUTION: ORIGINAL JACKET		REVIEWER	DIVISION FILE
R/D initialed by: Disc Supplement/NDA20263.S06 			

OCT 19 1995

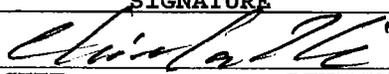
CHEMIST'S REVIEW		1. ORGANIZATION DMEDP, HFD-510	2. NDA NUMBER 20-263
3. NAME AND ADDRESS OF APPLICANT TAP Pharmaceuticals Inc. Bannockburn Lake Office Plaza 2355 Waukegan Road Deerfield, IL 60015		6. NONPROPRIETARY NAME Leuprolide acetate for depot suspension	4. SUPPLEMENT NUMBER, DATE Supplement S-006 12/30/94
5. NAME OF THE DRUG Lupron Depot PED	7. SUPPLEMENT PROVIDES FOR: Additional container-closure system (Pre-filled, Dual Chamber Syringe) filled with Lupron Depot and diluent.		8. AMENDMENTS/REPORTS, DATE Amendment 5/24/95 9/7/95
9. PHARMACOLOGICAL CATEGORY Inhibitor of gonadotropin secretion	10. HOW DISPENSED RX	RELATED IND/NDA/DMF DMF [] DMF [] NDA 19-732/S09 NDA 19-943/S02 NDA 19-263/S06	
12. DOSAGE FORM Microsphere Depot	13. POTENCY 7.5 mg, 11.25 mg and 15.0 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

- 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-009 of NDA #19-732.
- 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. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Chien-Hua Niu, Ph.D.		10/19/95

DISTRIBUTION: ORIGINAL JACKET REVIEWER DIVISION FILE
R/D initialed by:
Disc Supplement/NDA20263.S6A


10/19/95

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-263/S-006

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

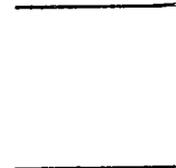
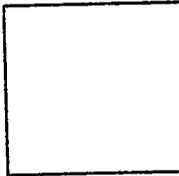
A. 1. NDA 19-732/S-009

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:



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

JAC 3/17/95

Redacted 11 page(s)

of trade secret and/or

confidential commercial

information from

Microbiology Review #1
S-006

JUN 29 1995

A-7.1
Consultative Review to HFD-510
DIVISION OF MEDICAL IMAGING, SURGICAL,
and DENTAL DRUG PRODUCTS; HFD-160

Microbiologist's Review #2
30 June 1995

- A. 1. NDA 19-732/S-009
NDA 20-011/S-006
NDA 19-943/S-002
NDA 20-263/S-006

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:



5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION: Lupron® Depot 7.5 mg is used for palliative treatment of advanced prostate cancer. Lupron® Depot 3.75 mg is indicated for the management of endometriosis and management of anemia caused by uterine fibroids. Lupron® Depot - PED (7.5 mg, 11.25 mg, 15 mg) is used for treatment of central precocious puberty.

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

2. DATE OF AMENDMENT: 24 May 1995

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: 9 June 1995

C. REMARKS: The amendment is a response to deficiencies found in the 20 March 1995 review of the Supplemental New Drug Application. The response to deficiencies is referenced by 3 additional Supplemental New Drug Applications, They are: NDA 20-011/S-006, NDA 19-943/S-002, and NDA 20-263/S-006. Therefore, this review applies to all four applications.

D. CONCLUSIONS: The application is approvable upon on the resolution of microbiology concerns. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of Letter to Applicant".

 29 June 1995
Paul Stinavage, Ph.D.

cc: Original NDA 19-732, NDA 20-011, NDA 19-943, and NDA 20-263
HFD-160/Stinavage/Consult File
HFD-510/Div File/L. Pauls
Drafted by: P. Stinavage
R/D initialed by P. Cooney

D. Hussong for PHC 6/29/95

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confidential commercial

information from

Microbiology Review #2

J
5-006

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:



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".


 Paul Stinavage, Ph.D. 4 October 1995

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

PAC 10/4/95

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of trade secret and/or

confidential commercial

information from

Microbiology Review#3
(S-006)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-263/S-006

CORRESPONDENCE

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

S-24-95
S-25-95
SCP 006 Af

AUG 10 1995

Tap Holdings, Inc.
Attention: Aruna Dabholkar, M.D.
Regulatory Products Manager
2355 Waukegan Road
Deerfield, IL 60015

A 71

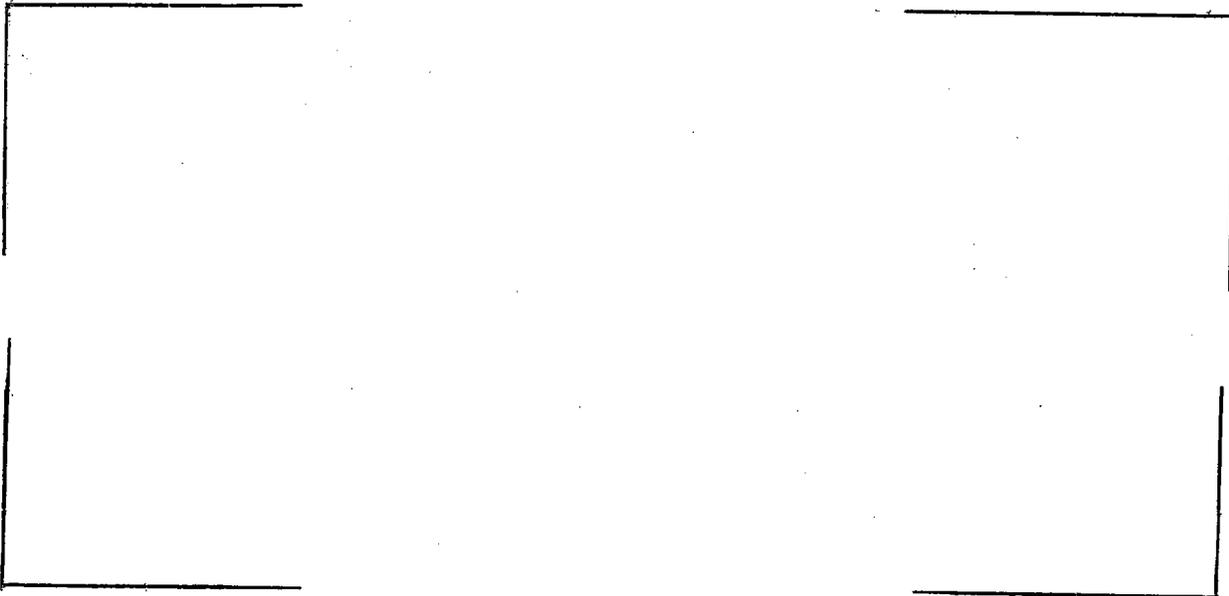
Dear Dr. Dabholkar:

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).

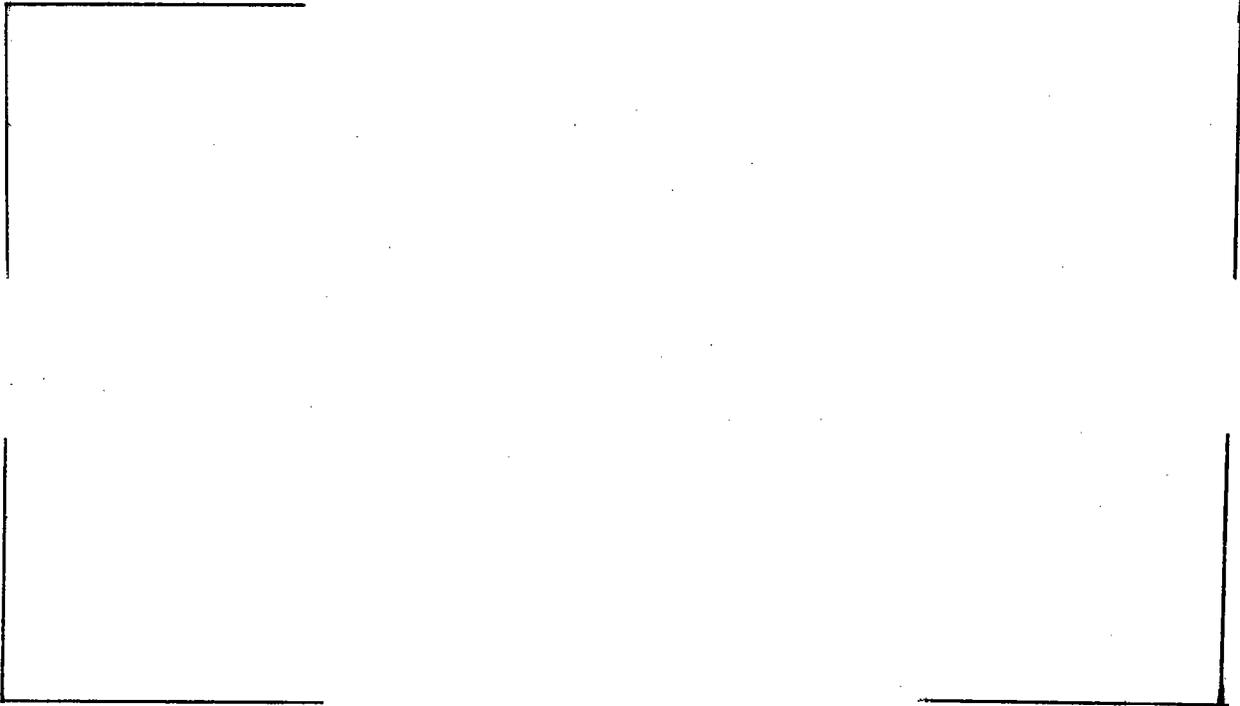
We also refer to your amendment dated May 24, 1995, submitted in response to our not approvable letter issued April 25, 1995.

We have completed our review of the Microbiology section of your submissions and have identified the following deficiencies:



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

Page 2

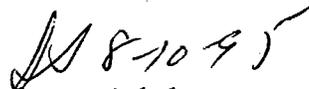


We would appreciate your prompt written response so we can continue our evaluation of your supplemental applications.

If you have any questions, please contact:

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

Sincerely yours,


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

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

Page 3

cc:

Original NDA
HFD-510/Div. Files
HFD-160/PStinavage
HFD-510/CNiu
DISTRICT OFFICE

drafted: LPauls/August 3, 1995/N19732ir.s09

Concurrences:

CNiu, YYChiu 08.07.95

INFORMATION REQUEST (IR)

LLP 8/10/95



TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

~~SUPPL NEW CONTAINER~~

SEP-006AC ORIGINAL

NDA SUPPL AMEND



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

*Noted
Priority Review
Completed
See Chg. Rev. for
SEP-006
CMI 10/19/95*

RE: Lupron Depot®-PED (leuprolide acetate for depot suspension)
NDA 20-263/S-006 (Prefilled Dual Chamber Syringe)
Amendment No. 001 (Response to Deficiency Letter)

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 006 for Prefilled Dual Chamber Syringe (additional container/closure system).

The complete response to the non-approvable letter dated April 25, 1995 is submitted to NDA 19-732, S-009, Amendment No. 001. We request you to cross refer to the amendment.

Attached is the FDA Form 356h.

Sincerely,

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

AD/pjp
Attachment

REVIEWS COMPLETED	
CSO ACTION:	
<input checked="" type="checkbox"/> LETTER	<input type="checkbox"/> MAIL
CSO INITIALS	DATE
<i>ADP</i>	<i>11/2/95</i>



TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

CRIS NEW CORALS
Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

SUPPL NEW CORRESP

ORIGINAL

May 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
5-16-95*

RE: Lupron Depot PED[®] (leuprolide acetate for depot suspension)
NDA 20-263/S-006

*Noted
CDE 5/17/95*

Dear Doctor Sobel:

We have reviewed your letter dated April 25, 1995. This letter is to inform you of our intent to file an amendment to the SNDA pursuant to 21 CFR § 314.120 (a) (1).

Please note that the plant inspection for this SNDA has been scheduled for May 29 - June 1, 1995. The deficiencies mentioned in the letter will be discussed with the inspectors at the site. We will follow-up with the amendment soon after.

*Noted
Kragan
5/17/95*

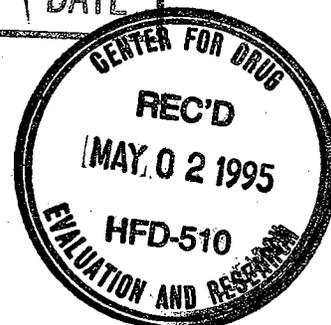
Sincerely,

[Signature]

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

AD/pjp
Attachment

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input checked="" type="checkbox"/> N.A.I.
CSO INITIALS	DATE
<i>UP</i>	<i>5/22/95</i>



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
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 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:

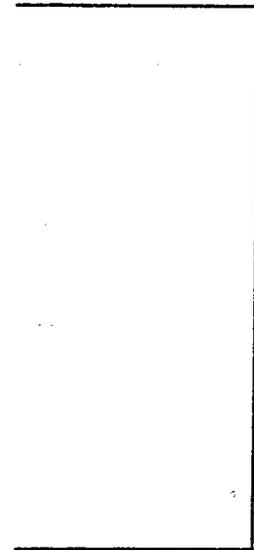
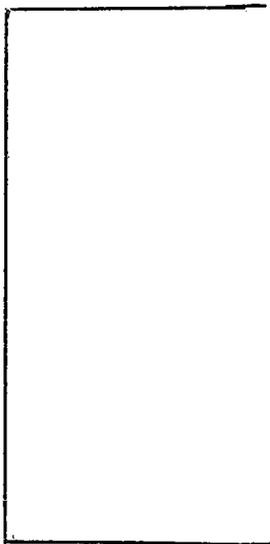
Manufacturing/Quality Control:

1.

2.

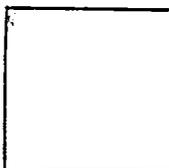
3.

4.



Microbiology:

1.



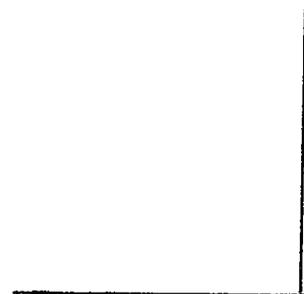
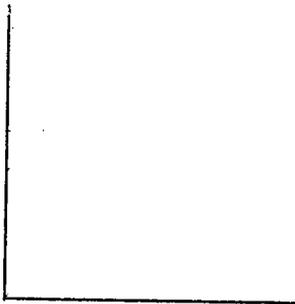
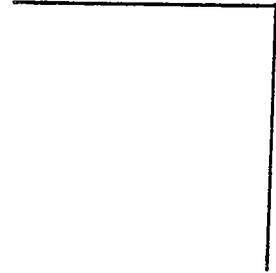
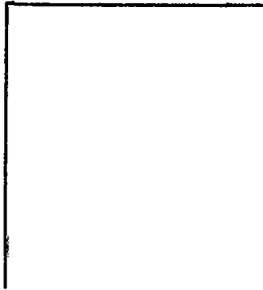
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of trade secret and/or

confidential commercial

information from

Correspondence (Not Approvable Letter)
(S-006) 4/25/95



Please note, additional information has been requested from the [redacted], the holder of DMF [redacted]. 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.

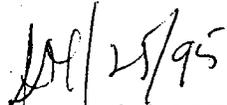
NDA 19-732/S-009
NDA 20-011/S-006
NDA 20-263/S-006

Page 5

If you have any questions, please contact:

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

Sincerely yours,



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:

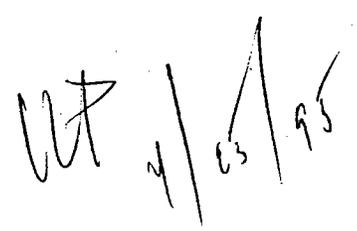
Original NDAs 19-732, 20-011, 20-263
HFD-510
DISTRICT OFFICE
HFD-80
HFD-160/PStinavich/PCooney
HFD-510/CNiu/YYChiu
HFD-510/L.L.Pauls

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

Concurrences:

CNiu, YYChiu 04.24.95

NOT APPROVABLE (NA)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date JAN 11 1995

NDA No. 20-263

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-PED

NDA Number: 20-263

Supplement Number: S-006

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,

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



TAP PHARMACEUTICALS INC.

NDA NO. 20263 REF. NO. 006

NDA SUPPL FOR SCP (w/draft) labeling

December 30, 1994

Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, Illinois 60015

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-PED® (leuprolide acetate for depot suspension)
NDA 20-263
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-PED® 7.5 mg, 11.25 mg and 15 mg. approved under NDA 20-263.

All the information required for this supplemental application is submitted under our NDA 19-732 (Lupron Depot® 7.5 mg) in the supplement of this date. 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: AD/pjp 4/26/95

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