CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20-517/S-001

Trade Name: LUPRON DEPOT 3 MONTH,22.5 mg

Generic Name:Leuprolide Acetate for Depot Suspension

Sponsor: Tap Holdings, Inc.

Approval Date:December 3, 1996

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APPLICATION: NDA 20-517/S-001

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter			X	
Final Printed Labeling			X	
Medical Review(s)			X	
Chemistry Review(s)	X			
EA/FONSI			X	
Pharmacology Review(s)			X	
Statistical Review(s)			X	
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)			X	
Bioequivalence Review(s)			X	
Administrative Document(s)			X	
Correspondence	X			

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Application Number: NDA 20-517/S-001

APPROVAL LETTER

APPROVED

DEC 3 1996

NDA 20-517/S-001

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

Dear Dr. Dabholkar:

Reference is made to your supplemental new drug application dated April 12, 1996, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot (leuprolide acetate for depot suspension) 3 month, 22.5 mg.

We also refer to your amendment dated May 21, 1996.

This supplemental application provides for a dual chamber syringe as a new container closure system.

We have completed the review of this supplemental application, as amended, and it is 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, please contact Mr. Alvis Dunson at 310-827-5260.

Sincerely yours,

MRhee 12/3/96

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader , DNDC II
@ Division of Reproductive and Urologic
Drug Products (HFD-580)
Office of New Drug Evaulation II
Center for Drug Evaluation and Research

cc:
Original NDA
HFD-580
HFD-580/MRhee/ADunson
HFD-80
HFD-232
DISTRICT OFFICE
HFD-222/YChiu
HFD-580/CKish/11.29.96/n20517ap.s1
concurrences:MRhee 12.3.96
SUPPLEMENT APPROVAL (S-001)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-517/S-001

CHEMISTRY REVIEW(S)

ORIGINAL

NOV 26 1996

CHEMIST'S REVIEW

1. Organization
DMEDP HFD-580

2. NDA Number
20-517

3. Name amd Address of Applicant
TAP Holdings Inc.
Bannockburn Lake Office Plaza
2355 Waukegan Rd
Deerfield, Il 60015

4. Supplement
S-001 —
4-12-96

5. Name of Drug
Lupron Depot, 3-month, 22.5mg

6. Nonproprietary Name
Leuploride acetate for depot suspension

7. Supplement Provides For
A dual chamber syringe as a new container closure system.

8. Amendment
5-21-96 (Micro. Responses)

9. Pharmacological Category
Gonadorelin agonist

10. How Dispensed
Rx

11. Related
19-732 (S-009)

12. Dosage form
Lyophilized powder to be reconstituted for Injection (IM)

13. Potency
22.5mg

14. Chemical Name and Structure
5-oxo-L-Pro-L-His-L-Trp-L-Ser-L-Tyr-D-Leu-L-Leu-L-Arg-N-ethyl-L-Prolinamide acetate

15. Comments:
This supplement dscribes a new container/closure system which is a

A similar dual chamber syringe (slightly smaller) was previously approved for NDA 19-732 (S-009). This supplement provides the following information: I) CMC information (vol. 6.1), II) Facilities and aseptic process validation (vol. 6.2), III) methods validation/samples/labels (vol.6.3). Consult for microbiology was sent on 5/28/96 and Microbiologist's review recommened approrval from sterility assurance point of view. EER was forwarded on 10/28/96 and returned with "Acceptable" rating (11/21/96).

16. Conclusion and Recommendation
This supplement can be approved from the chemistry point of view. Issue an approval letter.

17. Name
Moo-Jhong Rhee, Ph.D.

Reviewer's Signature

Date
11-21-96

Distribution
R/D initialed by
sl.260

Original Jacket

11/26/96

Reviewer

Division File

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APPLICATION NUMBER: NDA 20-517/S-001

CORRESPONDENCE

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

April 12, 1996

Bannockburn Lake Office Plaza
2355 Waukegan Rd.
Deerfield, IL 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

RE: Lupron Depot®-3 Month 22.5 mg
(leuprolide acetate for depot suspension)
NDA 20-517
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 Month 22.5 mg approved under NDA 20-517.

This supplement consists of 3 volumes labeled as Volume 1-3. Volume 1 contains all chemistry, manufacturing and controls information. Volume 2 contains information on facilities and aseptic process validations for review by CDER's Sterile Products Group. This volume is labeled as "Sterile Process Validation Package." Volume 3 contains the Methods Validation Package. Four copies of all three volumes are submitted.

Attached is the information required for this supplement.

Sincerely,

Aruna Dabholkar, M.D.
Regulatory Products Manager
(847) 317-4893

AD/pjp
Attachment

NDA SUPPL AMENDMENT ORIGINAL

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

May 21, 1996

Division of Metabolism and Endocrine Drug Products
Document Control Room 14B-19, HFD-510
Center for Drugs Evaluation & Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Lupron Depot® 3-Month, 22.5 mg (leuprolide acetate for depot suspension)
NDA 20-517
S-001, Amendment No. 001

Dear Doctor Sobel:

Pursuant to 21 CFR §314.60 (a), the Sponsor, TAP Holdings Inc., submits this amendment to the pending supplemental application 001 with the enclosed information.

This amendment is submitted as requested by Microbiology reviewer (Dr. Uratani) to clarify the sterile process validation documents and to respond to her questions regarding the validations.

The manufacturing process and the validation protocols submitted in this SNDA (001) are the same as the one submitted in our approved NDA 19-732, S-009 for Lupron Depot 7.5 mg The NDA 19-732, S-009 may be referred to for these documents. Please note that the current supplement (001) also contains the results of the validation studies performed on Lupron Depot-3 Month 22.5 mg, dual chamber prefilled syringe.

The responses to the reviewer's questions about sterilization validation of the diluent are attached.

Sincerely,

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

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

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
MAY 22 1996
HFD-510

AD/pjp

Attachment