CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-708

CHEMISTRY REVIEW(S)

Dunson

FEB - 5 1997

DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG PRODUCTS, HFD-580
Review of Chemistry, Manufacturing and Controls

NDA #: 20-708
CHEMISTRY REVIEW #: 2 **DATE REVIEWED:** Feb 5, 1997

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	3-6-96	3-8-96	3-13-96
AMENDMENT	5-1-96	5-2-96	

NAME & ADDRESS OF APPLICANT: TAP Holdings Inc.
2355 Waukegan Rd
Deerfield, IL 60015

DRUG PRODUCT NAME

Proprietary:	Lupron Depot-3 Month 11.25mg
Nonproprietary/Established/USAN:	Leuprolide acetate for depot suspension
Code Name/#:	TAP-144-SR, Abbott-43818
Chem.Type/Ther.Class:	3C

ANDA Suitability Petition / DESI / Patent Status: N/A [if applicable]

PHARMACOLOGICAL CATEGORY/INDICATION: LHRH agonist/Endometriosis
DOSAGE FORM: Lyophilized Powder to be reconstituted for Injection
STRENGTHS: 11.25mg
ROUTE OF ADMINISTRATION: Injection (SQ)
DISPENSED: _X_ Rx ___ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:
5-oxo-L-Pro-L-His-L-Trp-L-Ser-L-Tyr-D-Leu-L-Leu-L-Arg-N-ethyl-L-Prolinamide acetate

$C_{59}H_{84}N_{16}O_{12}.C_2H_4O_2$
MW = 1269.48

CONCLUSIONS & RECOMMENDATIONS:
Microbiology consult review (Jan 22, 1997. see the Attachment I) came with a recommendation of approval from sterility assurance point of view. FONSI was signed on Feb 1, 1997

There is no CMC pending issues and this NDA can be approved from chemistry point of view.

cc:
Org. NDA
HFD-580/Division File
HFD-580/MRhee/ADunson

Moo-Jhong Rhee, Ph.D.
ChemistryTeam Leader

filename: n.20708.#2

Dunson

DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG PRODUCTS, HFD-580
Review of Chemistry, Manufacturing and Controls

NDA #: 20-708
CHEMISTRY REVIEW #: 1 **DATE REVIEWED:** 12-23-96

DEC 2 3 1996

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	3-6-96	3-8-96	3-13-96
AMENDMENT	5-1-96	5-2-96	

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MW = 1269.48

CONCLUSIONS & RECOMMENDATIONS:
This NDA is approvable from chemistry, manufacturing, and controls point of view. EER was deemed "Acceptable" as of 6-21-96. Micro consult sent on 5-3-96 is still pending. EA consult sent on 12-23-96 for the concurrence of FONSI is pending.

cc:
Org. NDA
HFD-580/Division File
HFD-580/MRhee/ADunson

Moo-Jhong Rhee, Ph.D.
ChemistryTeam Leader

filename: NL. 212

SUPPORTING DOCUMENTS:

NDAs 19-010, 19732, 19943, 20-517
DMF
DMF

Consults:

Micro on 5-3-96.
EA on 12-23-96 for the concurrence of FONSI

REMARKS/COMMENTS:

This NDA was submitted for approval of Lupron Depot-3 Month 11.25mg for the management of endometriosis caused by uterine fibroids. The drug product is essentially the same as the previously approved Lupron Depot-3 months 22.5mg for the treatment of prostate cancer. The only difference is that the strength is reduced to 11.25mg by filling the vial with half the amount (22.5mg) of the approved drug.

Amendment dated 5-1-96 was submitted to provide EA and aseptic process validation.