

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-708

CHEMISTRY REVIEW(S)

Dunson

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

FEB - 5 1997

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:

☒ 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

C59H84N16O12.C2H4O2

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

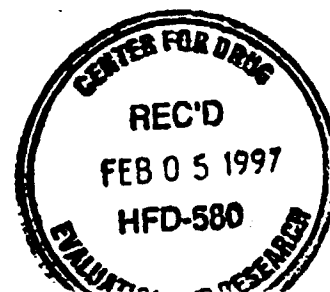
HFD-580/Division File

HFD-580/MRhee/ADunson



Moo-Jhong Rhee, Ph.D.
Chemistry Team 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 23 1996

| <u>SUBMISSION TYPE</u> | <u>DOCUMENT DATE</u> | <u>CDER DATE</u> | <u>ASSIGNED DATE</u> |
|-------------------------------|-----------------------------|-------------------------|-----------------------------|
| ORIGINAL | 3-6-96 | 3-8-96 | 3-13-96 |
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C59H84N16O12.C2H4O2

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.
Chemistry Team Leader

filename: NL. 212

SUPPORTING DOCUMENTS:

NDA's 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.