CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-708/S-005

CORRESPONDENCE

NDA 20-708/S-005

Food and Drug Administration
Rockville MD 20857

Tap Holdings Inc.
2355 Waukegan Road
Deerfield, IL 60015

APR 16 1998

Attention: Aruna Dabholkar, M.D.,
Associate Director, Regulatory Affairs

Dear Dr. Dabholkar:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Lupron Depot® 3 Month 11.25 mg (leuprolide acetate for depot suspension)
NDA Number:	20-708
Supplement Number:	S-005
Date of Supplement:	April 10, 1998
Date of Receipt:	April 13, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on June 12, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation II
Attention: Document Control Room 17B-20
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

Lana Pauls
Chief, Project Management Staff
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:

Original NDA 20-708/S-005
HFD-580/Div. Files
HFD-580/CSO/A. Dunson

SUPPLEMENT ACKNOWLEDGEMENT

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

Bannockburn Lake Office Plaza
2355 Waukegan Rd
Deerfield, IL 60015

February 8, 1999

Division of Reproductive and Urologic Drug Products, **HFD-580**
Document Control Room 17B-20
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Lupron Depot®-3 Month 11.25 mg
(leuprolide acetate for depot suspension)

NDA 20-708, S-005
Serial No. 003

Dear Dr. Rarick:

This is to inform you that all the safety data from study M95-506 was submitted in the 4-month safety update dated August 7, 1998. Since the study is complete there is no new safety data available at this time.

Sincerely,

Aruna Dabholkar, M.D., RAC
Associate Director, Regulatory Affairs
(847) 317-4893
(847) 317-5795 (fax)

AD/mea

Note 2/10/99
Safety update
reviewed in
August

SE8-005
BM

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

kburn Lake Office Plaza
a.kegan Rd.
d, IL 60015

December 3, 1998

Division of Reproductive and Urologic Drug Products, HF
Document Control Room 17B-20
Center for Drug Evaluation & Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Lupron Depot®-3 Month 11.25 mg
NDA 20-708, S-005
Amendment No. 002

Dear Dr. Rarick:

Submitted is the information requested by Dr. Safran. A desk copy of this submission is sent directly to Dr. Safran.

Sincerely,

Aruna Dabholkar
Associate Director, Regulatory Affairs
(847) 317-4893

AD:dk

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

ORIGINAL

NDA SUPP AMEND

August 7, 1998

Division of Reproductive and Urologic Products, HFD-580 SE8-005 SU
Document Control Room 17B-20
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

gl. 8/18/98

8/18/98

RE: Lupron Depot®-3 Month 11.25 mg
(leuprolide acetate for depot suspension)
NDA: 20-708, S-005
Amendment No. 001

4-Month Safety Update

Dear Dr. Rarick:

The Sponsor, TAP Holdings Inc., submits this amendment (Four Month Safety Update) to the Supplemental Application under the provisions of Section 505(I) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.50(d)(5)(vi)(b).

This amendment contains safety data from the follow-up period of clinical study M96-506.

Sincerely,

Aruna Dabholkar, M.D.
Associate Director, Regulatory Affairs
(847) 317-4893

AD/mea

Attachment

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

ORIGINAL

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

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

April 10, 1998

Division of Reproductive and Urologic Products, HFD-580
Document Control Room 17B-20
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

SE8
NDA NO. 20708 REF. NO. SR-005
NDA SUPPL FOR Draft

RE: Lupron Depot®-3 Month 11.25 mg (leuprolide acetate for depot suspension)
NDA 20-708, S-005
Supplemental Application for Prior Approval

Dear Dr. Rarick:

Pursuant to CFR § 314.70 (b), TAP Holdings Inc. Submits this Supplemental Application for approval of the revised package insert for Lupron Depot®-3 Month 11.25 mg. The package insert is revised to include the results of the Phase IV Study. Four draft copies of the revised package insert are attached.

The annotated package insert clearly shows the additional information from the results of Study M96-506 added to the following sections: **PHARMACOKINETICS, CLINICAL STUDIES, ADVERSE REACTIONS** and the subsection of *changes in bone density*.

The complete summary report for Study M96-506 is attached along with the drug metabolism report and the new assay validation report. As discussed earlier with the reviewers (Dr. Safran and Dr. Barnett), the summary reports are being submitted electronically in Microsoft Word with the tables in Excel. All diskettes are submitted separately as desk copies to the two reviewers.

The check (no. 052887) for the total user fees was mailed on April 3, 1998.

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

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
APR 13 1998
HFD-580

Background Information: Study M96-506 is the Study to satisfy the Phase IV commitment for NDA 19-943 and also the requirement of a comparative PK/PD data for NDA 20-708 (see attached letter from the Division). The comparative safety and efficacy of the two formulations was also evaluated during the study.

For any queries or information regarding this application please contact me at (847) 317-4893.

Sincerely,

Aruna Dabholkar, M.D.
Associate Director, Regulatory Affairs
(847) 317-4893
(847) 317-5795 (fax)