CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19732/S012

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date FEB 27 1996

NDA No. 19-732

TAP HOLDINGS INC.
2355 Waukegan Road
Deerfield, IL 60015

Attention: Aruna Dabholkar, M.D., Regulatory Products Manager

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Lupron Depot 7.5 mg

NDA Number: 19-732

Supplement Number: S-012

Date of Supplement: February 19, 1996

Date of Receipt: February 20, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on APRIL 20, 1996 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 Metabolic and Endocrine Drug Products
Attention: Document Control Room
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours,

/S/

Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office Drug Evaluation II
Center for Drug Evaluation and Research

NDA SUPPL AMENDMENT

SLR-012 AF

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

Feb 19, 1996 → CDE

April 15, 1996

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: NDA 19-732 **Final Printed Labels**
Lupron Depot 7.5 mg (leuprolide acetate for depot suspension)
SNDA 012, Amendment No. 001

Dear Dr. Sobel,

Attached are the fifteen copies of the final printed package inserts and all labels, etc. for Lupron Depot 7.5 mg.

The enclosed package insert and labels have been revised as indicated in our SNDA 012 dated February 19, 1996.

Please note that the vial labels and vial cartons are not revised but are submitted here to complete the set.

Sincerely,

Aruna Dabholkar
Regulatory Product Manager
(847) 317-4893

AD/pjp

CENTER FOR
RECD
APR 17 1996
HFD-510
EVALUATION AND RESEARCH

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

4/9/96

CSO INITIALS DATE

NDA NO. 19732 SUPP. NO. 012

NDA SUPPL FOR SLR

ORIGINAL

NDA SUPPLEMENT

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

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

AJ 7/22/96

February 19, 1996

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

to be discussed
Renewed A Copy
Anne Dee A Copy
3-4-96

RE: Lupron Depot® 7.5 mg (leuprolide acetate for depot suspension)
NDA 19-732
Supplemental Application - Changes Being Effected

Noted
MPK 7/18/96

Dear Dr. Sobel:

Pursuant to CFR § 314.70 (c) (2), TAP Holdings Inc. submits this Supplemental Application to report the revision of the package insert, ampule labels and kit labels for Lupron Depot 7.5 mg. Four copies of the revised labels and package insert are attached.

The annotated package insert clearly shows the changes and additions. The summary of major changes is as follows:

1. The ADVERSE REACTION section is revised to include reports from post marketing surveillance.

2. The diluent ampules are changed from 1.5 mL to 2 mL for convenience of marketing all Lupron Depot products (1 Month and 3 Month) with one ampule (2mL).

Please note that the 2 mL ampule is approved in NDA 20-517 (Lupron Depot®-3 Month 22.5 mg). The amount of diluent used for reconstitution of Lupron Depot 7.5 mg remains the same (1 mL) as approved under NDA 19-732. This change was discussed with Dr. Niu in September 1995, and we were advised to report it as "Changes Being Effected" after approval of the 2 mL ampules in NDA 20-517.

The new labels and the package insert will be implemented on March 1, 1996. The 12 copies of the final printed labels and package insert will be submitted as soon as these are available.

Sincerely,

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

AD/pjp
Attachment

REVIEWS COMPLETED

CSO ACTION:

☐ LETTER ☐ N.A.I.

CSO INITIALS DATE