

**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



TAP HOLDINGS INC.  
parent of TAP Pharmaceuticals Inc.

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

*Handwritten:* 19, 1996 → 198 12, 1996  
10/5/96  
10/11/96  
10/11/96

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.

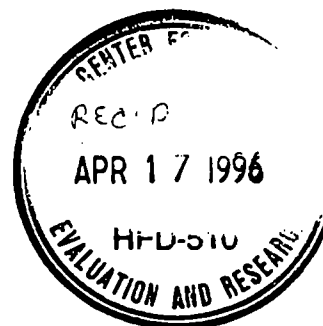
Please note that the vial labels and vial cartons are not revised but are submitted here to complete the set.

Sincerely,

Aruna Dabholkar  
Regulatory Product Manager  
(847) 317-4893

AD/pjp

REVIEWS COMPLETED	
CSO ACTION:	
<input checked="" type="checkbox"/> LETTER	<input checked="" type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE





TAP HOLDINGS INC.  
parent of TAP Pharmaceuticals Inc.

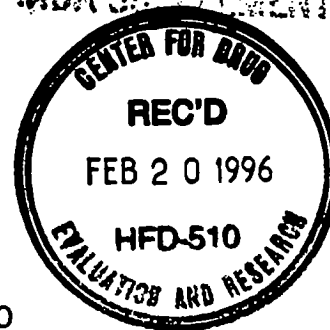
annockburn Lake Office Plaza  
2355 Waukegan Rd.  
Deerfield, IL 60015

NDA NO. 19732

NDA SUPPL FOR SLR

ORIGINAL

NDA SUPPLEMENT



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  
revised  
Home Dec 8 copy  
3-4-96*

RE: Lupron Depot® 7.5 mg (leuprolide acetate for depot suspension)

NDA 19-732

Supplemental Application - Changes Being Effectuated

*dated  
m/K 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:

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

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 Effectuated" 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