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APPLICATION NUMBER: NDA 20011/S14

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

APR 8 1998

CLINICAL PHARMACOLOGY and BIOPHARMACEUTICS REVIEW

NDA: 20-011

Compound: Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension)

Submission Date: September 22, 1997 (Supplement No. 014)

Sponsor: TAP Holdings, Inc.

Type of Submission: Labeling Supplement

Reviewer: K. Gary Barnette, Ph.D.

Summary:

On October 10, 1990 Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension) was approved for the indication of management of endometriosis. Subsequently, this product was approved for treatment of anemia associated with uterine leiomyomata (uterine fibroids) in women who failed iron therapy on March 30, 1995.

On September 22, 1997 the sponsor submitted supplement 014 to NDA 20-011 to propose the addition of data to the product label that proposes a benefit of "add-back" hormonal replacement therapy for the treatment of endometriosis in the menopausal effects and osteoporotic effects associated with administration of Lupron Depot® 3.75 mg.

Recommendation:

The proposed product labeling for Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension), submitted to NDA 20-011 on September 22, 1997 has been reviewed by the Office of Clinical Pharmacology and Biopharmaceutics/Division of Pharmaceutical Evaluation II (OCPB/DPEII). It should be noted that the sponsor does not propose any changes in the **Pharmacokinetic** subsection (Absorption, Distribution, Metabolism, Excretion, Special Populations or Drug-Drug Interactions) of the **CLINICAL PHARMACOLOGY** section of the product label. Therefore, OCPB/DPEII has no further comment.

ISI

4/8/98

K. Gary Barnette, Ph.D.
Division Pharmaceutical Evaluation II
Office of Clinical Pharmacology and Biopharmaceutics

RD initialed by Angelica Dorantes, Ph.D., Team Leader *AD 4/8/98*
FT signed by Angelica Dorantes, Ph.D., Team Leader *A Dorantes 4/8/98*

cc: NDA 20-011, HFD-580, HFD-580 (Safran, Dorantes), HFD-870 (M.Chen 13B-17, Dorantes, Barnette), Drug file (Barbara Murphy).