



NDA 20-263/S-024

TAP Pharmaceuticals, Inc.  
Attention: Jessie Lee, PhD  
Principal Regulatory Advisor  
675 North Field Drive  
Lake Forrest, IL 60045

Dear Dr. Lee:

Please refer to your supplemental new drug application dated August 28, 2003, received , submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron (leuprolide acetate) injection, 5 mg/mL.

This “Changes Being Effected” supplemental new drug application provides for labeling revisions to several sections of the Lupron injection package insert for the treatment of central precocious puberty in order to increase consistency with other Lupron package inserts.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (see attached document).

The final printed labeling (FPL) must be identical to the electronic draft labeling submitted on March 2, 2004. In addition, it must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement 20-263/S-024." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.  
Director  
Division of Metabolic and Endocrine Drug  
Products, HFD-510  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Lupron Injection 5.0 mg/mL package insert for Central Precocious Puberty

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Monika Johnson  
3/2/04 04:38:06 PM