



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-263/S-033

Abbott Endocrine Inc., a wholly owned subsidiary of Abbott Laboratories
Attention: Heather Perritano, M.S.
Associate Director, Regulatory Affairs
200 Abbott Park Road, D-PA76/AP30-1NE
Abbott Park, IL 60064

Dear Ms. Perritano:

Please refer to your supplemental new drug application dated February 28, 2008, received February 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot-PED/Lupron Injection (leuprolide acetate/injection/depot suspension).

We acknowledge receipt of your submissions dated March 3 and 10, 2008, and May 13 and 14, 2009.

This "Changes Being Effected" supplemental new drug application provides for:

- the removal of Factrel from the Contraindications section of the package inserts, since Factrel is no longer marketed in the United States
- updates to the How Supplied section, as well as other editorial changes made to the package inserts.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Package inserts

1. Lupron Injection, 5 mg/mL (For Pediatric Use)
2. Lupron Depot-Ped, 7.5 mg, 11.25 mg and 15 mg, prefilled, dual-chamber syringes

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

/s/

Mary Parks

6/24/2009 10:38:52 PM