DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-263/S-030

Abbott Endocrine, Inc., a wholly owned subsidiary of Abbott Laboratories
Attention: David C. Ross, Pharm.D., MBA
Director, Global Pharmaceutical Regulatory Affairs
100 Abbott Park Road, D-PA76/AP30-1NE
Abbott Park, IL 60064

Dear Dr. Ross:

Please refer to your supplemental new drug application dated April 27, 2007, received April 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron Depot-Ped (leuprolide acetate for depot suspension).

We acknowledge receipt of your submission dated January 3, 2008.

This "Changes Being Effected" supplemental new drug application provides for the addition of the phrase "Pediatric Use Only" to both the mixing instructions and the clamshell kit (container) labels for Lupron Depot-Ped products, as well as a redesign of the kit labels.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (mixing instructions, immediate container labels) submitted January 3, 2008.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-263/S-030**". Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolism and Endocrinology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Enclosure: Clamshell kit (container) labels, Instructions on How to Mix and Administer

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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

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