DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-943/S-029
NDA 20-011/S-036

Abbott Laboratories
Attention: David C. Cross, Pharm.D., M.B.A.
Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Dr. Cross:

Please refer to your supplemental new drug applications (NDAs) dated November 24, 2008, received November 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LUPRON DEPOT® (leuprolide acetate for depot suspension) Injection, 3.75 mg.

These "Changes Being Effected" supplemental new drug applications provide for (1) the addition of the term "convulsion" to the **Postmarketing** subsection of the **ADVERSE REACTIONS** section and (2) revision to the **HOW SUPPLIED** section of the Package Insert for each of the above NDAs.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 19-943/S-029 and NDA 20-011/S-036."

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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Scott Monroe

6/2/2009 10:44:55 AM