DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019010/S-033
NDA 019732/S-031/S-035/S-036
NDA 020517/S-024/S-028/S-029

SUPPLEMENT APPROVAL

Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-6188

Attention: Natalie Tolli, B.Pharm, M.S.
Director, Global Pharmaceutical Regulatory Affairs

Dear Ms. Tolli:

Please refer to your supplemental new drug applications dated December 18, 2006, February 28 and November 24, 2008, received December 19, 2006, February 29 and November 25, 2008, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lupron® Injection, Lupron Depot® 7.5 mg, Lupron Depot® 3 M 22.5 mg, and Lupron Depot® 4 M 30 mg (leuprolide acetate for depot suspension).

We acknowledge receipt of your submissions dated December 19, 2006, and March 3, 2008, received December 20, 2006, and March 4, 2008, respectively.

These "Changes Being Effected" supplemental new drug applications provide for the removal of Factrel from the **Contraindications** section of the package inserts, addition of myocardial infarction, diabetes and convulsion to the **Adverse Events, Postmarketing** section of the package inserts as well as other editorial revisions.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

1. Delete all current references in the package insert and replace them with the following safe handling references at the time of next printing:

    a. NIOSH Alert: Preventing occupational exposures to antineoplastic and other hazardous drugs in healthcare settings. 2004. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165.

b. OSHA Technical Manual, TED 1-0.15A, Section VI: Chapter 2. Controlling Occupational Exposure to Hazardous Drugs. OSHA, 1999. http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

c. American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63:1172-1193.

d. Polovich, M., White, J. M., & Kelleher, L.O. (eds.) 2005. Chemotherapy and biotherapy guidelines and recommendations for practice (2nd. ed.) Pittsburgh, PA: Oncology Nursing Society.

LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days from the date of this letter, amend all pending supplemental applications for this NDA, including pending CBE supplements, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions listed above approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package inserts 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to these NDAs and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Christy Cottrell, Regulatory Project Manager, at (301) 796-4256.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20517	SUPPL-29	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON DEPOT
NDA-20517	SUPPL-28	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON DEPOT
NDA-20517	SUPPL-24	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON DEPOT
NDA-19732	SUPPL-36	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON DEPOT
NDA-19732	SUPPL-35	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON DEPOT
NDA-19732	SUPPL-31	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON DEPOT
NDA-19010	SUPPL-33	ABBOTT ENDOCRINE INC SUB ABBOTT LABORATORIES	LUPRON

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

/s/

ROBERT L JUSTICE
04/28/2010