DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019010/S-036
NDA 019732/S-037
NDA 020517/S-031

SUPPLEMENT APPROVAL

Abbott Endocrine Inc., a wholly owned subsidiary of Abbott Laboratories
Attention: Jean M. Conaway, RPh, RAC, MBA
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road, Dept. PA76/Bldg. AP30-1NE
Abbott Park, IL 60064-6157

Dear Ms. Conaway:

Please refer to your Supplemental New Drug Applications (sNDA) dated November 17, 2010, received November 17, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following GnRH agonists:

Application	Supplement	Drug Name
NDA 019010	S-036	Lupron (leuprolide acetate) Injection
NDA 019732	S-037	Lupron Depot 7.5 mg (leuprolide acetate for depot suspension)
NDA 020517	S-031	Lupron Depot-3 M 22.5 mg (leuprolide acetate for depot suspension) and Lupron Depot-4 M 30 mg (leuprolide acetate for depot suspension)

We also refer to our approval letter dated January 14, 2011, which contained the following error: "Lupron Depot-6 M 45 mg (leuprolide acetate for depot suspension)" should not have been included in the table listing the Lupron products since the efficacy supplement for this presentation had not been approved when NDA 020517/S-031 was approved. The labeling attached is unchanged from the labeling in the January 14, 2011, letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain January 14, 2011, the date of the original approval letter.

We acknowledge receipt of your amendments dated December 20 (NDAs 019732 and 020517) and December 30, 2010 (NDA 19010).

We also refer to our letter dated October 20, 2010, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for GnRH agonists. This information pertains to the risk of diabetes and certain cardiovascular diseases (heart attack, sudden cardiac death, and stroke).

These supplemental new drug applications provide for revisions to the labeling for Lupron (leuprolide acetate) products listed above. The agreed upon changes to the language included in our October 20, 2010, letter are as follows (additions are noted by underline and deletion are noted by ~~strikethrough)~~.

Under WARNINGS AND PRECAUTIONS section of the full prescribing information (or in the PRECAUTIONS section for non-PLR format):

Hyperglycemia and an increased risk of developing diabetes have been reported in men (b) (4) receiving GnRH agonists. Hyperglycemia may represent development of diabetes mellitus or worsening of glycemic control in patients with diabetes. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH agonist and manage with current practice for treatment of hyperglycemia or diabetes.

Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. The risk appears low based on the reported odds ratios, and should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice.

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.

CONTENT OF 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 and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling

[21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on 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.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Susan Jenney, Regulatory Project Manager, at (301) 796-0062.

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 of Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

/s/

AMNA IBRAHIM
01/14/2011
For Dr Robert Justice