

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

203696Orig1s000

Trade Name: Lupaneta Pack

Generic Name: Leuprolide acetate for depot suspension and norethindrone acetate tablets

Sponsor: Abbot Endocrine, Inc.

Approval Date: December 14, 2012

Indications: For the initial management of the painful symptoms of endometriosis and for the management of recurrence of the symptoms.

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APPROVAL LETTER



NDA 203696

NDA APPROVAL

Abbott Endocrine, Inc.
Attention: Gennadiy Koev, Ph.D.
Manager, Regulatory Affairs - PPG
200 Abbott Park Road
Dept PA77/Bldg AP30-1NE
Abbott Park, IL 60064-6157

Dear Dr. Koev:

Please refer to your New Drug Application (NDA) dated and received February 15, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LUPANETA PACK® (leuprolide acetate for depot suspension and norethindrone acetate tablets) 3.75mg/5mg and 11.25mg/5mg.

We acknowledge receipt of your amendments dated March 30, April 10, May 22, June 14, July 3, and 10, September 24, October 2, 18, and 19, November 16 and 29, and December 6, 10, 11, and 13, 2012. This new drug application provides for the use of LUPANETA PACK® (leuprolide acetate for depot suspension and norethindrone acetate tablets) for the initial management of the painful symptoms of endometriosis and for the management of recurrence of the symptoms. LUPANETA PACK is available in two strengths/dose regimens: 3.75 mg leuprolide acetate for depot suspension administered once-monthly and 5 mg norethindrone acetate tablets taken daily for 30 days, and 11.25 mg leuprolide acetate for depot suspension administered once every three months and 5 mg norethindrone acetate tablets taken daily for 90 days.

We have completed our review of this application, as amended. It is 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and immediate-container labels that are identical to the enclosed carton and immediate-container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 203696.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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, 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 Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Kim Shiley, R.N., B.S.N., Regulatory Project Manager, at (301) 796-2117.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling

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

/s/

AUDREY L GASSMAN
12/14/2012