DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21778/S-016

SUPPLEMENT APPROVAL

Par Pharmaceutical, Inc.
Attention: Meredith Selby
Director, Regulatory Affairs
One Ram Ridge Road
Spring Valley, NY 10977

Dear Ms. Selby:

Please refer to your Supplemental New Drug Application (sNDA) dated April 3, 2013, received April 4, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Megace ES (megestrol acetate) Oral Suspension, 625 mg/5 ml.

We acknowledge receipt of your email dated May 1, 2013, that includes the agreed-upon labeling.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to be consistent with the labeling changes made to the listed drug, Megace Oral Suspension 40 mg/mL. Specifically, the following revisions have been made:

1. Modification of the USE IN SPECIFIC POPULATIONS section (8), Use in Women subsection (8.6) to include the following text: "Megace ES is a progesterone derivative, which may induce vaginal bleeding in women."

2. Revision of the OVERDOSAGE section (10) to include the following text: "In post-marketing experience, limited reports of overdose have been received. Signs and symptoms reported in the context of overdose included diarrhea, nausea, abdominal pain, shortness of breath, cough, unsteady gait, listlessness, and chest pain. There is no specific antidote for overdose with Megace® ES oral suspension. In case of overdose, appropriate supportive measures should be taken."

3. Editorial revisions (formatting, punctuation, and spelling) have been made which do not impact the meaning of the labeling.

We have completed our review of this supplemental application. 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), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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 that includes labeling changes 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling (Package Insert)

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

/s/

MARY H PARKS
05/14/2013