DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-778/S-002, S-003

Par Pharmaceuticals, Inc.
Attention: Michele Bonomi-Huvala
Senior Director, Regulatory Affairs
One Ram Ridge Road
Spring Valley, NY 10977

Dear Ms. Bonomi-Huvala:

Please refer to your supplemental new drug applications dated September 15, 2006 (S-002) and October 10, 2006 (S-003), received September 18, 2006 (S-002) and October 11, 2006 (S-003), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Megace ES (megestrol acetate) Oral Suspension.

We acknowledge receipt of your submissions dated October 17, and November 14, 2006, submitted to Supplement -003.

These supplemental new drug applications provide for the following:

-Supplement -002 provides for revisions to the Pharmacokinetic Properties subsection of the CLINICAL PHARMACOLOGY section of the package insert to include information on the effect of food on the rate and extent of absorption of megestrol acetate.

-Supplement -003 provides for the addition of an alternate packaging site ((b) (4)---------- to package a new 5 mL Hospital Unit Dose container/closure configuration, and associated labeling revisions.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text. Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-778/S-002, S-003**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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: Package Insert
Unit-Dose Container Label

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

/s/

Mary Parks
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