DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-778

Par Pharmaceutical Inc.
Attention: Michelle Bonomi-Huvala
Senior Director, Regulatory Affairs Research & Development
300 Tice Boulevard
Woodcliff Lake, New Jersey 07677

Dear Ms. Bonomi-Huvala:

Please refer to your new drug application (NDA) dated June 29, 2004, received June 29, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Megace ES (megestrol acetate) Oral Suspension 125 mg/mL.

We acknowledge receipt of your submissions dated August 20 and 27, September 22, October 20(2) and 21, November 4(2), and December 29, 2004, and January 20, 27 and 28, February 7, 16, 24, and 25, March 16(2), 17, and 22, April 7, 12(2), 14, 15, 25, 26, and 28, May 5, 10 and 26, and June 17, 2005.

This new drug application provides for the use of Megace ES (megestrol acetate) Oral Suspension 125 mg/mL for treatment of anorexia, cachexia or an unexplained significant weight loss in AIDS patients.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (package insert submitted May 26, 2005**,** immediate container labels submitted May 26, 2005**)**.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

Submit two copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Holly Wieland, Regulatory Project Manager at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Package Insert
Container Labels (25 mL and 150 mL bottles)

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

/s/

David Orloff

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