NDA 011839/S-078

APPROVAL LETTER

Pfizer Inc.
Attention: Michelle Patel, R.Ph.
Senior Manager, Pfizer Global Regulatory Sciences
66 Hudson Boulevard East
New York, NY 10001

Dear Ms. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 10, 2012, pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Provera (medroxyprogesterone acetate tablets).

This "Changes Being Effected" supplemental new drug application provides for corrections to authorized generic packaging components/artwork.

APPROVAL & 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.

We note that your October 10, 2012, submission includes final printed labeling (FPL) for your prescribing information, and patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 011839/S-078.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Olubusola Fasanmi, Regulatory Business Process Manager, at (301) 796 - 0191.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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