DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-246/S-025

Pfizer, Inc.
Attention: Alan Traettino
Regulatory Affairs
235 East 42nd Street 150/7/16
New York, NY 10017

Dear Mr. Traettino:

Please refer to your supplemental new drug application (NDA) submitted September 8, 2004, received September 9, 2004, under section 505(b) of the Federal Food, Drugs, and Cosmetics Act for DEPO-PROVERA ® Contraceptive Injection (medroxyprogesterone acetate injectable suspension) IM.

We also acknowledge receipt of your submissions dated September 28 and 30, October 13 and 25, and November 4, 2004.

This "Changes Being Effected" supplemental new drug application provides for changes to the physician and patient insert of the label.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 4, 2004 and as enclosed.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-246/S-025." Approval of this submission by FDA is not required before the labeling is used.

We request that you submit a copy of the "Dear Health Care Professional" letter communicating important information about this drug product to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
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 Charlene Williamson, Regulatory Project Management Staff, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Donna Griebel

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