DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-839/S-071

Pfizer, Inc.
Attention: Corinne Gamper, Director/Team Leader
Worldwide Regulatory Strategy
235 East 42nd Street 150/7/9
New York, NY 10017

Dear Ms. Gamper:

Please refer to your supplemental new drug application dated March 29, 2007, received March 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROVERA® (medroxyprogesterone acetate tablets, USP).

We acknowledge receipt of your submission dated September 27, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes to the physician and patient package inserts in response to the published data from the Women's Health Initiative.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental NDA 11-839/S-071."

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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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic 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/

Scott Monroe

9/28/2007 04:31:52 PM