DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-583/S-011

Pharmacia & Upjohn Company
c/o Pfizer Global Pharmaceuticals
Attention: Clara Arrocain, M.D.
Associate Director
235 East 42nd Street 685/18/16
New York, NY 10017

Dear Dr. Arrocain:

Please refer to your supplemental new drug application dated and received January 15, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for depo-subQ provera 104™ (medroxyprogesterone acetate injectable suspension 104mg/0.65ml).

We also acknowledge receipt of your submissions dated April 8, and June 25, 2009.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (1) replacement of the current needle-stick protection device with a Terumo® Surguard™ needle, (2) revision of carton labeling, and (3) revision of the **Instruction for Use of depo subQ provera 104 FOR SUBCUTANEOUS ADMINISTRATION ONLY** and **HOW SUPPLIED** sections of the Physician Labeling.

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

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the submitted labeling dated June 25, 2009. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 Manager, at (301) 796-1025.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
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

7/15/2009 12:26:38 PM