**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-583/S-001

Pfizer, Inc.
Attention: Jennifer Bingaman
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 20017

Dear Ms. Bingaman:

Please refer to your supplemental new drug application dated March 7, 2005, received March 8, 2005, 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.

This "Changes Being Effected" supplemental new drug application provides for changes to the description of the needle and plastic cover in the physician labeling, updating the trademark, and an addition of the RSS barcode.

We 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 agreed-upon labeling text.

If you have any questions, call Charlene Williamson, Regulatory Project Manager, 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

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/s/

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Donna Griebel

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