



NDA 21-583/S-003

Pfizer Global Pharmaceuticals
Attention: Corinne Gamper
Director/Team Lead
235 East 42nd Street
New York, NY 10017

Dear Ms. Gamper:

Please refer to your supplemental new drug application dated May 6, 2005, received May 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for depo-subQ provera 104 (medroxyprogesterone acetate injectable suspension) 104 mg/0.65 ml.

This supplemental new drug application is intended to incorporate the labeling approved under NDA 21-584 for both indications into NDA 21-583.

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 labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling and/or submitted labeling (package insert and patient package insert submitted May 6, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-583/S-003.**" 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 (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.
Acting Deputy 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

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