



NDA 20-246/S019

Pfizer Inc.
(Formerly Pharmacia & Upjohn)
Attention: Mr. Daniel Chirby
Senior Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Chirby:

Please refer to your supplemental new drug application dated December 4, 2002, received December 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Depo-Provera® Contraceptive Injection (medroxyprogesterone acetate injectable suspension, USP).

This “Changes Being Effected” supplemental new drug application provides for a needle guard to be provided on the needle in the approved packaging and revised labeling (attached).

We completed our review of this supplemental new drug application and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Karen Anderson, N.P., Regulatory Project Manager, at (301) 827-4259.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Deputy Director
Division of Reproductive and Urologic Drug
Products (HFD-580)
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Donna Griebel
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