



NDA 20-246/S-013

Pfizer Global Pharmaceuticals
Attention: Jennifer Bingaman
235 East 42nd Street
Mail Stop 605/5/14
New York, NY 10017

Dear Ms. Bingaman:

Please refer to your supplemental new drug application dated November 11, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Depo-Provera® Contraceptive Injection (medroxyprogesterone acetate injectable suspension, USP).

We acknowledge receipt of your submissions dated February 10, April 12, and August 1, 2005.

We also refer to a telephone conversation between representatives of your firm and this division during which you were informed that the patient brochure is considered promotional labeling and will, therefore, not be approved as part of this supplement. Because it is not considered approved labeling, there is no requirement that the patient brochure be distributed with the drug product.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the physician package insert and the patient package insert).

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 these submissions "**FPL for approved supplement NDA 20-246/S-013.**" Approval of these submissions 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) 796-2310.

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
10/28/2005 04:21:30 PM