NDA 20-895/S-003

Pfizer Inc
Attention: Rita Wittich
Director, Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated July 24, 1998, received July 27, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viagra™ (sildenafil citrate) tablets.

We acknowledge receipt of your submissions dated October 6, and November 10, 17, and 24, 1998.

This supplemental new drug application provides for changes in the **CLINICAL PHARMACOLOGY**, **CONTRAINDICATIONS**, **WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS** sections of the package insert, and a health care professional letter highlighting these changes.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you of the commitment specified in our discussion on November 23, 1998, to revise (b)((b)(4)(CC)----------

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 24, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material.

For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-895/S-003." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Kim Colangelo, Project Manager, at (301) 827-4260.

Sincerely,

Lisa D. Rarick, M.D.
Director
Division of Reproductive
and Urologic Drug Products (HFD-580)
Office of Drug Evaluation II
Center for Drug Evaluation and Research