DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-354/SLR-044
NDA 17-355/SLR-046
NDA 17-875/SLR-032
NDA 17-876/SLR-031

Pfizer, Inc.
Attention: Ms. Tara Feehan
Project Manager
235 East 42nd Street 150/7/5
New York, NY 10017

Dear Ms. Feehan:

Please refer to your supplemental new drug applications dated November 9, 2001, received November 13, 2001 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

1. NDA 17-354 Loestrin Fe 1/20 norethindrone acetate & ethinyl estradiol tablets, USP and Ferrous Fumarate) tablets

2. NDA-17-355 Loestrin Fe 1.5/30 (norethindrone acetate & ethinyl estradiol tablets, USP and Ferrous Fumarate) tablets

3. NDA 17-875 Loestrin 21 1.5/30 (norethindrone acetate & ethinyl estradiol) tablets

4. NDA 17-876 Loestrin 21 1/20 (norethindrone acetate & ethinyl estradiol) tablets.

We acknowledge receipt of the amendments to your submissions dated April 1, 2003.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the Pfizer Inc. name to all package configurations.

We completed our review of these applications as amended and are approved effective on the date of this letter. The final printed labeling (FPL) must be identical to submitted labeling (package insert, patient package insert submitted, immediate container and carton labels) on November 9, 2001 and April 1, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available. 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, please call Karen Anderson, Regulatory Project Manager, at Ph. (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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Donna Griebel

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