



NDA 16-954/S-092

Johnson & Johnson Pharmaceutical Research and Development
Agent for: Ortho-McNeil Pharmaceutical, Inc.
Attention: Tracy Healy, R.N.
Senior Regulatory Associate
Global Marketed Products
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Healy:

Please refer to your supplemental new drug application dated June 10, 2002, received June 11, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ortho Micronor[®] Tablets (norethindrone).

This supplemental new drug application provides for an incorrect statement regarding usage on the patient labeling.

We have completed the review of this supplemental application 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, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling dated June 10, 2002.

Please submit the FPL electronically 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, 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 16-954/S-092." Approval of this submission by FDA is not required before the labeling is used.

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

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, N.P., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
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/

Daniel A. Shames
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