



NDA 21-180/S-008

Ortho-McNeil Pharmaceutical, Inc.
Attention: Patricia Capaccione, R.Ph.
Senior Associate, Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, New Jersey 08869-0602

Dear Ms. Capaccione:

Please refer to your supplemental new drug application dated October 7, 2003, received October 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ortho Evra[®] (norelgestromin and ethinyl estradiol transdermal system).

This supplemental new drug application provides for specific disposal instructions for the patient of the used transdermal contraceptive system.

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 October 7, 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

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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