DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-954/S-101

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Agent for: Ortho McNeil Pharmaceutical, Inc.
Attention: Susan Nemeth
Director, Regulatory Affairs
920 U.S. Highway 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Nemeth:

Please refer to your supplemental new drug application dated and received December 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO MICRONOR (norethindrone) Tablets.

We acknowledge receipt of your submissions dated January 22, 2008, and April 30, 2008.

We also refer to our letter dated August 14, 2006, wherein we requested you to revise the **PRECAUTIONS** section, Nursing Mothers subsection to indicate that isolated post-marketing cases of decreased milk production have been reported in women using progestin-only oral contraceptives. This supplemental new drug application provides for the requested change.

We have 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 enclosed agreed-upon labeling text.

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
Suite 12B05
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, call Jennifer Mercier, Chief, Project Management Staff, at (301) 796-0957.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
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

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