DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-653/S-045
NDA 19-697/S-041

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

Dear Ms. Mulligan:

Please refer to your supplemental new drug applications dated July 5, 2007, received July 5, 2007 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO-CYCLEN® (250 µg norgestimate/35µg ethinyl estradiol) Tablets and ORTHO TRI-CYCLEN® (180, 215 and 250 µg norgestimate/35 µg ethinyl estradiol) Tablets.

We also refer to your amendments dated November 15, 2007 and May 21, 2008.

These supplemental new drug applications provide for (1) an alternate manufacturing process and a formulation change and (2) changes to the DESCRIPTION and HOW SUPPLIED sections of the Package Insert.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon enclosed 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 text. 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) 796-0997.

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

5/30/2008 01:56:11 PM