DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-653/S-037
NDA 19-697/S-034

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Cynthia Chianese
Director, North America Regional Liaison, Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Ms. Chianese:

Please refer to your supplemental new drug applications dated September 27, 2004, received September 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ortho-Cyclen® (norgestimate/ethinyl estradiol) and Ortho Tri-Cyclen® (norgestimate/ethinyl estradiol) Tablets.

Your submission of November 7, 2006, constituted a complete response to our June 30, 2006, action letter.

These supplemental new drug applications provide for the following:

- Revisions to the CLINICAL PHARMACOLOGY and INDICATIONS and USAGE sections of the label pertaining to the acne indication.
- An updated PHARMACOKINETICS section with the following subsections: Absorption, Distribution, Metabolism, Excretion, Special Populations, Renal and Hepatic Impairment, and Drug-Drug Interactions.
- Revisions to the Pediatric Use subsection of the PRECAUTIONS section.

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 labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert that was agreed to on February 9, 2007.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 19-653/S-037 and NDA 19-697/S-034**." Approval of these submissions by FDA is not required before the labeling is used.

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 John C. Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 796-0932.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon Package Insert

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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