DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180/S-014

Johnson & Johnson Pharmaceutical
Research & Development, LLC
Attention: Lillian Malahias, M.S.
920 U.S. Highway 202, P.O. Box 300
Raritan, NJ 08869

Dear Ms. Malahias:

Please refer to your supplemental new drug application dated July 30, 2004, received August 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO-EVRA® (norelgestromin/ethinyl estradiol transdermal system).

We also acknowledge receipt of your submission dated November 23, 2004.

This supplemental new drug application provides (b)(4) norelgestromin (NGMN) drug substance.

We completed our review of this application and the application is approved

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 Charlene Williamson, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader for
Division of Reproductive and Urologic Drug Products - (HFD-580)
Division of New Drug Chemistry II
Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Amit K. Mitra

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Amit Mitra for Moo-Jhong Rhee