DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180/S-015

Johnson & Johnson Pharmaceutical
Research & Development, L.L.C.
Attention: Patricia Capaccione, R.Ph.
920 Route 202, P.O. Box 300
Raritan, NJ 08869

Dear Ms. Capaccione:

Please refer to your supplemental new drug application dated November 3, 2004, received November 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO EVRA® (norelgestromin/ethinyl estradiol transdermal system).

We acknowledge receipt of your submission dated May 5, 2005.

This supplemental new drug application provides for changes in the physician and patient inserts, and the carton and pouch labeling that indicate that the exposure to ethinyl estradiol associated with ORTHO EVRA® is higher than that which results from a 20 microgram oral ethinyl estradiol contraceptive pill.

We 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 attached physician and patient labeling and the carton and pouch labeling as amended per our teleconference on May 6, 2005.

If you have any questions, call Charlene Williamson, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Deputy Director
Division of Reproductive and Urologic Drug 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/

Donna Griebel

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