DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-180/S-033 **SUPPLEMENT APPROVAL**

Johnson & Johnson Pharmaceutical Research & Development, LLC
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, NJ 08869

Dear Dr. Nemeth:

Please refer to your supplemental new drug application dated and received on March 12, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ORTHO EVRA® (norelgestromin/ethinyl estradiol transdermal system).

We also refer to your amendment dated August 17, 2009.

This "Prior Approval" supplemental new drug application provides for (1) a revision to Table 5 and the accompanying text in the **WARNINGS** section of the Physician Label and (2) an updated reference to the study report that provided the revised data represented in Table 5. This revision is based on a reanalysis of epidemiologic data, which resulted in a revision of the Odds Ratio for venous thromboembolism risk and the confidence interval around the Odds Ratio reported in Table 5 from 2.4 (1.1 – 5.5) to 2.5 (1.1 – 5.5).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit content of labeling [21CFR 314.50(1)] 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 label. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21180	SUPPL-33	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	ORTHO EVRA(NORELGESTROMIN/ETHINYL ESTRAD

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SCOTT E MONROE
09/11/2009