DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-180/S-029 **APPROVAL LETTER**

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs
920 U.S. Highway 202
P.O. Box 300
Raritan, NJ 08869

Dear Dr. Nemeth:

Please refer to your supplemental new drug application dated and received on May 7, 2008, 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 submissions dated June 12 and November 3, 2008, and January 29 and July 28, 2009.

Your submission of January 29, 2009, constituted a complete response to our November 21, 2008, Action Letter.

This supplemental new drug application includes the following changes to the Physician Package Insert:

1. Replacing the term "significant hypertension" with actual blood pressure values in the CONTRAINDICATIONS section.
2. Providing more complete guidance to healthcare providers regarding the use of ORTHO EVRA® in women with hypertension in the WARNINGS section, Elevated Blood Pressure subsection.
3. Extensive editorial revisions to provide for use of MedDRA terminology and a more user-friendly format in the ADVERSE REACTIONS section, Clinical Trial Experience and Postmarketing Experience subsections.

This supplemental new drug application also includes revisions to the Detailed Patient Labeling, SIDE EFFECTS OF ORTHO EVRA® section to conform with the revisions in the Physician Package Insert.

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 submitted labeling dated July 28, 2009. 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

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
07/29/2009