DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180/S-028, S-030 & S-031

Johnson & Johnson Pharmaceuticals Research & Development, L.L.C.
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs
Mature Product Support
920 Route 202, P.O. Box 300
Raritan, NJ 08869

Dear Dr. Nemeth:

Please refer to your supplemental new drug applications dated and received April 17 (S-028), June 24 (S-030), and July 31 (S-031), 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for ORTHO EVRA® (norelgestromin/ethinyl estradiol transdermal system).

We also refer to your submissions dated October 20, 2008, for supplements 028, 030, and 031.

Supplement 028 provides for revisions to (1) the Drug Interactions subsection of the PRECAUTIONS Section of the Physician Insert and (2) the Drug Interactions subsection of the GENERAL PRECAUTIONS Section of the Detailed Patient Labeling.

Supplement 030 provides for revision of the disposal instructions for used patches in (1) the Transdermal Contraceptive System Overview subsection of the DOSAGE AND ADMINISTRATION Section and the Special Precautions for Storage and Disposal subsection of the HOW SUPPLIED Section of the Physician Insert, (2) the HOW TO USE ORTHO EVRA Section and the Special Precautions for Storage and Disposal subsection of the OTHER INFORMATION Section of the Detailed Patient Labeling, and (3) the container labeling.

Supplement 031 provides for changes in the WARNINGS Section of the Physician Insert to include 14 months of data on new cases from the Boston Collaborative Drug Surveillance Program study analyzing the risk of venous thromboembolism.

We have completed our review of these applications, as amended, and the applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 14 days of the date of this letter, submit content of labeling [21CFR 314.50(1)] in structured product labeling (SPL) format, as describer at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the submitted labeling dated October 20, 2008. Upon receipt and verification, we will transmit that version to the National Library of medicine for public dissemination.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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) 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

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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