DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180/S-022

Johnson & Johnson Pharmaceuticals Research & Development, L.L.C.
Attention: Cynthia Chianese
Director, North America Regional Liaison
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Ms. Chianese:

Please refer to your supplemental new drug application dated July 19, 2006, received July 20, 2006, 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 September 18, 2006.

This supplemental new drug application provides for changes to the "INDICATIONS AND USAGE" and "WARNINGS" sections of the physician insert, and to the "OTHER CONSIDERATIONS BEFORE USING ORTHO EVRA" and the "Risk of Developing Blood Clots" sections of the patient insert. The changes describe the results from two epidemiology studies designed to assess the risk of venous thromboembolism in users of ORTHO EVRA compared to users of oral contraceptives containing norgestimate and 35 micrograms of ethinyl estradiol.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agree-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-180/S-022**." Approval of this submission by FDA is not required before the labeling is used.

We note that you plan to notify health care providers about this labeling change. When you issue the letter communicating this important information (i.e., the "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.
Acting 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

9/20/2006 10:06:12 AM