DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180/S-019

Johnson & Johnson Pharmaceutical
Research & Development, L.L.C.
Attention: Mary Christian, Pharm.D., R.A.C.
920 US Route 202
Raritan, NJ 08869

Dear Ms. Christian:

Please refer to your supplemental new drug application dated August 29, 2005, received August 30, 2005, 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 October 27, November 8 and 9, 2005.

These "Changes Being Effected" supplemental new drug applications provide for changes to *Description*, *Pharmacokinetics*, *Indications and Usage*, *Warning*, and *Dosage and Administration* sections of the Physician Insert and *Description, Other Considerations before using ORTHO EVRA®*, and *How to Use ORTHO EVRA®* in the Patient Detail Labeling.

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

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-180/S-019**." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA

5600 Fishers Lane
Rockville, MD 20857

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) 796-2130.

Sincerely,

{See appended electronic signature page}

Daniel Shames, 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/

Daniel A. Shames

11/10/2005 04:31:53 PM