



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-180/S-020

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.  
Attention: Cynthia Chianese,  
Director, Regulatory Affairs  
P.O. Box 300  
Raritan, N.J. 08869-0602

Dear Ms. Chianese:

Please refer to your supplemental new drug application dated November 16, 2005, received November 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO EVRA® (norelgestromin/ethinyl estradiol).

This supplemental new drug application provides for changes to the Physician Insert, Carton and Pouch labeling that are consistent with the changes approved on November 10, 2005 to the Physician and Patient Inserts.

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 agreed-upon labeling text.

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-020.**" Approval of this submission by FDA is not required before the labeling is used.

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}*

Scott Monroe, M.D.  
Deputy 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 Monroe  
5/17/2006 05:04:45 PM