



NDA 021180/S-034

SUPPLEMENT APPROVAL

Johnson & Johnson Pharmaceuticals Research & Development
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs
1000 U.S. Highway 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Nemeth:

Please refer to your supplemental new drug application dated May 29, 2009, received June 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ORTHO EVRA[®] (norelgestromin and ethinyl estradiol).

We acknowledge receipt of your submissions dated June 10, and November 6, and 25, 2009.

This "Prior Approval" supplemental new drug application provides for changes to the following sections of the Physician Insert (PI) and DETAILED PATIENT LABELING (additions are underlined):

1. In the CONTRAINDICATIONS section of the PI, addition of the following bulleted contraindication:
 - Known thrombophilic conditions
2. In the DETAILED PATIENT LABELING: Who Should Not Use ORTHO EVRA section, addition of the following bulleted condition:
 - An inherited problem that makes your blood clot more than normal
3. In the ADVERSE REACTIONS, Postmarketing Experience section of the PI, addition of dysguesia to adverse drug reactions identified during postmarketing experience
4. In the DETAILED PATIENT LABELING: Side Effects of ORTHO EVRA[®] Section 7, Other Side Effects, addition of abnormal taste
5. In the CLINICAL PHARMACOLOGY section of the PI, the Drug Interactions section was deleted and moved to PRECAUTIONS: Section 8, Drug Interactions

6. In the PRECAUTIONS: Section 8, Drug Interactions section,
 - Reformatting for improved readability
 - Addition of non-nucleoside reverse transcriptase inhibitors as a class of drugs that can significantly change (increase or decrease) the plasma concentrations of estrogen and progestin
 - Addition of voriconazole, fluconazole, grapefruit juice, and rosuvastatin as additional examples of drugs or foods that may increase the plasma concentration of ethinyl estradiol
7. In the DETAILED PATIENT LABELING: General Precautions Section 5, Drug Interactions, addition of herbal products

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 required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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) 7965-1025.

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21180	SUPPL-34	ORTHO MCNEIL JANSSEN PHARMACEUTICA LS INC	ORTHO EVRA(NORELGESTROMIN/ETHI NYL ESTRAD

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
12/01/2009