DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021180/S-035 **SUPPLEMENT APPROVAL**

Johnson & Johnson Pharmaceuticals Research & Development, L.L.C.
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Nemeth:

Please refer to your supplemental new drug application, dated October 9, 2009, and received on October 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ORTHO EVRA® (norelgestromin/ethinyl estradiol transdermal system).

We acknowledge receipt of your submissions dated January 28 and April 9, 2010.

This "Prior Approval" supplemental new drug application provides for (1) a revision to Table 5, which is titled "Estimates (Odds Ratios) of Venous Thromboembolism Risk in Current Users of ORTHO EVRA® Compared to Oral Contraceptive Users," and the accompanying text in the WARNINGS section of the Physician Labeling and (2) an update of the references that support the revision of Table 5. The revision of Table 5 is based on an additional 24 months of data from the i3 Ingenix Study and data from a new post-marketing study conducted by the Boston Collaborative Drug Surveillance Program (BCDSP). The additional data from the i3 Ingenix Study revises the Odds Ratio for venous thromboembolism risk and the confidence interval around the Odds Ratio reported in Table 5 from 2.5 (1.1 – 5.5) to 2.2 (1.2 – 4.0).

This supplemental new drug application also provides for revision of (1) the wording of the Special Precautions for Storage and Disposal subsection of the OTHER INFORMATION section in DETAILED PATIENT LABELING and (2) NDC numbers in the HOW SUPPLIED SECTION of Physician Labeling.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "**SPL for approved NDA 021180/S-035**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

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

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.

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 Health 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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21180	SUPPL-35	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	ORTHO EVRA(NORELGESTROMIN/ETHINYL 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
04/13/2010