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APPLICATION NUMBER:

21-180/S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-180/S-004

Johnson & Johnson Pharmaceutical Research & Development
Attention: Christopher Kowtna
Associate Director, Regulatory Affairs
1000 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Dear Mr. Kowtna:

Please refer to your supplemental new drug application dated May 15, 2002, received May 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO-EVRA™ (norelgestromin/ethinyl estradiol transdermal system).

This "Prior Approval" supplemental new drug application provides for an alternate site for conducting various manufacturing operations such as weighing, storage of drug substance, excipients, packaging componenets, and drug product, including the QC release and stability testing of the drug substances and drug product.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader, for the
Division of Reproductive and Urologic Drug Products,
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