CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-180/S-004

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180

PRIOR APPROVAL SUPPLEMENT

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Christopher C. Kowtna
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Mr. Kowtna:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	ORTHO-EVRA™ (norelgestromin/ethinyl estradiol transdermal system)
NDA Number:	21-180
Supplement number:	S-004
Date of supplement:	May 15, 2002
Date of receipt:	May 16, 2002

This supplemental application was submitted as a "Supplement – Prior Approval." The appropriateness of reporting the proposed change(s) as changes being effected in 30 days is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 16, 2002 in accordance with 21 CFR 314.101(a). The primary user fee goal date will be September 16, 2002. The secondary user fee goal date will be November 16, 2002.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Attention: Division Document Room, 17B20
5600 Fishers Lane
Rockville, Maryland 20857

If you have any question, call me at (301) 827-4260.

Sincerely,

Jennifer Mercier
Regulatory Project Manager
Division of Reproductive and Urologic Drug 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/

Jennifer L. Mercier
5/20/02 10:07:37 AM

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