CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-180/S-005

ADMINISTRATIVE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-180

PRIOR APPROVAL SUPPLEMENT

Ortho-Mcneil Pharmaceutical, Inc.
Attention: Christopher C. Kowtna, Associate Director
CMC /Regulatory Affairs
1000 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

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 and ethinyl estradiol) Transdermal Patch and 150 mcg norelgestromin, 20 mcg ethinyl estradiol
NDA Number:	21-180
Supplement number:	S-005
Date of supplement:	May 31, 2002
Date of receipt:	June 3, 2002

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 August 3, 2002 in accordance with 21 CFR 314.101(a).

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, contact me at (301) 827-4260.

Sincerely,

Jennifer Mercier
Regulatory Health 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
6/10/02 10:22:54 AM