

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 21-241/S-003**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-241

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.  
Attention: Sandy Rathborne  
Manager, Regulatory Affairs  
1000 Route 202 South  
P.O. Box 300  
Raritan, New Jersey 08869-0602

Dear Ms. Rathborne:

Please refer to your supplemental new drug application dated November 22, 2002, received November 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ortho Tri-Cyclen<sup>®</sup> Lo (norgestimate/ethinyl estradiol) Tablets.

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for a new alternate manufacturing site for the drug substance, Ethinyl Estradiol, USP.

We completed our review of this supplemental new drug application and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Karen Anderson, N.P., Regulatory Project Manager, at (301) 827-4259.

Sincerely,

{See appended electronic signature page}

David T. Lin, Ph.D.  
Chemistry Team Leader for  
Division of Reproductive and Urologic Drug Products  
(HFD-580)  
DNDC II, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

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/s/

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David T. Lin  
1/3/03 09:46:27 AM  
I concur.