

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-180

MICROBIOLOGY REVIEW(S)

THIS SECTION
WAS
DETERMINED
NOT
TO BE
RELEASABLE

2 pages

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: NDA 21180/000
Stamp: 21-DEC-2000 Regulatory Due: 21-OCT-2001
Applicant: JOHNSON RW
920 RT 202 SOUTH
RARITAN, NJ 088690670

Priority: S
Org Code: 580
Action Goal:
District Goal: 22-AUG-2001
Brand Name: ORTHO
EVRA(NORELGESTROMIN/ETHINYL
ESTRAD
Established Name:
Generic Name: NORELGESTROMIN/ETHINYL
ESTRADIOL
Dosage Form: FLM (TRANSDERMAL SYSTEM)
Strength: NRG/EE (150/20 MCG/DAY)

FDA Contacts: A. MITRA (HFD-580) 301-827-4238 , Review Chemist

Overall Recommendation:

ACCEPTABLE on 11-OCT-2001 by M. GARCIA (HFD-322) 301-594-0095

Establishment:

[Redacted]

DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 26-MAR-2001
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: [Redacted]

Establishment:

[Redacted]

DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 04-JUN-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities: [Redacted]

Establishment:

[Redacted]

DMF No:
AADA No:

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 09-APR-2001

Responsibilities: [Redacted]

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: _____ DMF No: _____
AADA No: _____

Profile: **CSN** OAI Status: **NONE** Responsibilities: _____
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **27-MAR-2001**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: _____ DMF No: _____
AADA No: _____

Profile: **TDP** OAI Status: **NONE** Responsibilities: _____
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **02-MAY-2001**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: _____ DMF No: _____
AADA No: _____

Profile: **CTL** QAI Status: **NONE** Responsibilities: _____
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-MAR-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: _____ DMF No: _____
AADA No: _____

Profile: **CTL** OAI Status: **NONE** Responsibilities: _____

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

TESTER

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-MAR-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: **2211100** DMF No:
ORTHO PHARMACEUTICAL CORP AADA No:
1000 RTE 202
RARITAN, NJ 08869

Profile: **CTL** OAI Status: **NONE** Responsibilities: **DRUG SUBSTANCE RELEASE**
Last Milestone: **OC RECOMMENDATION** **TESTER**
Milestone Date: **09-JUL-2001** **DRUG SUBSTANCE STABILITY**
Decision: **ACCEPTABLE** **TESTER**
Reason: **DISTRICT RECOMMENDATION**

Establishment: **2242831** DMF No:
ORTHO PHARMACEUTICAL CORP AADA No:
NUMBER 1 CAMPUS DR
SOMERSET, NJ 08873

Profile: **CTL** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE OTHER TESTER**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **03-MAY-2001**
Decision: **WITHHOLD**
Reason: **FACILITY NOT DOING FUNCTION**

Establishment: DMF No:
ORTHO-MCNEIL PHARMACEUTICA AADA No:
701 GALVESTON DRIVE
REDWOOD CITY, CA 94063

Profile: **TDP** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE**
Last Milestone: **OC RECOMMENDATION** **MANUFACTURER**
Milestone Date: **09-OCT-2001** **FINISHED DOSAGE STABILITY**
Decision: **ACCEPTABLE** **TESTER**
Reason: **DISTRICT RECOMMENDATION**

Establishment: DMF No:
AADA No:

Profile: **TDP** OAI Status: **NONE** Responsibilities:

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **07-MAY-2001**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

**APPEARS THIS WAY
ON ORIGINAL**

NDA 21-180

**ORTHO EVRA®
(norelgestromin/ethinyl estradiol) Transdermal Patch**

**R.W. Johnson Pharmaceutical Research Institute
1, 4S**

**PM: Jennifer Mercier
HFD-580
7-4260**

**Submission Date: December 21, 2000
Primary Goal Date: October 21, 2001
Secondary Goal Date: December 21, 2001**

Methods Validation

Methods have not yet been validated.

/S/
1/2 1/1