

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-180/S-005

CHEMISTRY REVIEW

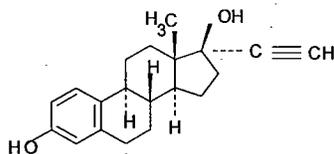
DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG PRODUCTS

REVIEW OF CHEMISTRY MANUFACTURING AND CONTROLS

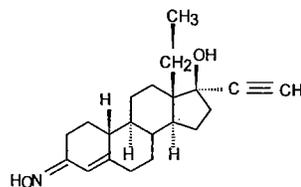
CHEMIST'S REVIEW #1

1. NDA NUMBER: 21-180
2. NAME AND ADDRESS OF APPLICANT
Johnson & Johnson Pharmaceutical Research & Development LLC
920 Route 202 South
Raritan, NJ 08869-0602
3. SUPPLEMENT NUMBER/DATE/DATE ASSIGNED
SCS-005/5-31-02/06-03-02
4. NAME OF THE DRUG: ORTHO EVRA
5. NONPROPRIETARY NAME: Norelgestromin/Ethinyl estradiol Transdermal Drug Delivery System
6. SUPPLEMENT PROVIDES FOR: A change in the acceptance criteria for _____ of the drug substance norelgestromin
7. AMENDMENTS/REPORTS/ DATE: None
8. PHARMACOLOGICAL CATEGORY
Combination estrogen/progestin, prevention of pregnancy.
9. HOW DISPENSED
Prescription
10. RELATED IND/NDA/DMF/SUPPLEMENT
None
11. DOSAGE FORM : Transdermal
12. POTENCY
Norelgestromin/Ethinyl estradiol (6.0 mg/0.75 mg per 20 cm²) delivering 150 µg norelgestromin, and 20 µg ethinyl estradiol per day.
13. CHEMICAL NAME AND STRUCTURE

Norelgestromin - (17 α)-17-hydroxy- 13-ethyl-18,19-dinorpregn-4-en-20-yn-3-one-3-oxime
Ethinyl estradiol - 19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol, (17 α)



Ethinyl estradiol
Molecular wt: 296.40



Norelgestromin
Molecular weight: 327.47

14. COMMENTS

The acceptance criteria for the ~~_____~~ of the drug substance norelgestromin are proposed to be changed from ~~_____~~ The sponsor claims that the acceptance criteria were set erroneously via a typographical error prior to NDA approval. The Chemistry Review #1, and #2 by Dr. A. K. Mitra, dated 12-OCT-2001 and 08-NOV-2001 suggest that the acceptance criteria can be widened based on the available data.

15. CONCLUSIONS AND RECOMMENDATIONS:

The supplement may be approved with respect to CMC. Please issue an approval letter.

Reviewed By: Amit K. Mitra, Ph.D.

R/D INIT. BY: Moo-Jhong Rhee, Ph.D

CC: A. K. MITRA/HFD-580
M.J.RHEE/HFD-580
J. Mercier/HFD-580
NDA 21-180

2 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

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/s/

Amit K. Mitra
6/17/02 04:40:16 PM
CHEMIST

Moo-Jhong Rhee
6/17/02 05:00:46 PM
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