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RESEARCH**

*APPLICATION NUMBER:*  
**203752Orig1s000**

**MEDICAL REVIEW(S)**

## CLINICAL REVIEW

Application Type NDA  
Application Number 203752  
Priority or Standard Standard

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Division/Office Division of Reproductive and  
Urologic Products  
(DRUP)/Office of Drug  
Evaluation III (ODE III)

Reviewer Name Phill H. Price, M.D.  
Review Completion Date September 24, 2012

Established Name Estradiol transdermal system  
(Proposed) Trade Name Minivelle  
Therapeutic Class Estrogen  
Applicant Noven Pharmaceuticals, Inc.

Formulation Transdermal Patch  
Dosing Regimen 0.0375 mg per day twice  
weekly initially allowing for  
titration upward (0.05 mg,  
0.075 mg, and 0.1 mg of  
estradiol per day if necessary  
depending upon relief of

	symptoms
Indication	Treatment of Moderate to Severe Vasomotor symptoms due to menopause
Intended Population(s)	Healthy Postmenopausal Women

Template Version: [March 6, 2009](#)

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