

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

021187Orig1s021s022

CHEMISTRY REVIEW(S)

1. Chemistry Review: 1		2. Division: HFD-580	NDA Number: 21187
3. Name and Address of Applicant: Organon USA Inc. One Merck Drive PO Box 100 Whitehouse Station, NJ 08889		4. Supplement(s): SLR PA Number: S-021 (Efficacy) S-022 (SLR) Date(s): 30-Aug-2012 (SDN 791) for S021 20-Dec-2012 (SDN 815) for S022	
5. Name of Drug: NuvaRing		6. Nonproprietary name: Etonogestrel and ethinyl estradiol	
7. Supplement Provides for Efficacy supplement to add results of the "Transatlantic Active Surveillance on Cardiovascular Safety of NuvaRing (TASC)" study and change approved label to Physicians Labeling Rule format.			8. Amendment(s): SDN 817 dated 20-Dec-2012 SDN 827 dated 09-Jan-2013 SDN 845 dated 12-Mar-2013 SDN 877 dated 04-Sep-2013
9. Pharmacological Category: Progestin and estrogen	10. How Dispensed: R _x	11. Related Documents: N/A	
12. Dosage Form: Vaginal Ring	13. Potency: 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol which releases on average 0.12 ^(b) mg/day of etonogestrel and 0.015 ⁽⁴⁾ mg/day of ethinyl estradiol		
14. Chemical Name and Structure: etonogestrel (13-ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-4-en-20-yn-3-one) ethinyl estradiol (19-nor-17 α -pregna-1,3,5(10)-trien-20-yne-3,17-diol)			
<div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;"> <p>ETONOGESTREL</p> <p>C₂₂H₂₈O₂</p> </div> <div style="text-align: center;"> <p>ETHINYL ESTRADIOL</p> <p>C₂₀H₂₄O₂</p> </div> </div>			
15. Comments This supplements seek approval for addition of results from the "Transatlantic Active Surveillance on Cardiovascular Safety of NuvaRing (TASC)" study and to change the label to the PLR format. The label in PLR format is transferred from the approved label with minor editorial changes only. There are a few clarification comments that will be conveyed to the applicant when the label is sent by OND.			
16. Conclusion: This Supplement is recommended for approval from the CMC perspective, with the recommended changes made in the eRoom and captured in the Review Notes. As this is OND-managed, any correspondence with the applicant will come from OND.			
17. Name: Donna F. Christner, Ph.D.		Signature:	Date:
18. Concurrence: Thomas F. Oliver, Ph.D.		Signature:	Date:

Review Notes

This PA labeling supplement seeks approval for a label conversion into PLR format. The label in PLR format is primarily transferred from the approved label, but some changes were made and are captured below.

Relevant sections in the submitted label draft were reviewed for accuracy from CMC perspective:

- 1 Indications and Usage
- 2 Dosage and Administration
- 3 Dosage Forms and Strengths
- 11 Description
- 16 How supplied/Storage and Handling

The majority of the sections are acceptable from the CMC perspective, as there are only minor editorial changes when compared with the previous approved label. Some modifications were made to the DESCRIPTION section. The sections are reproduced below.

(b) (4)



2 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DONNA F CHRISTNER
09/10/2013

THOMAS F OLIVER
09/10/2013