CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203752Orig1s000

OTHER REVIEW(S)

SEALD Addendum: Selected Requirements of Prescribing Information Review of the End-of-Cycle Prescribing Information

Product Title	**MINIVELLE (estradiol transdermal system)**
Applicant	Noven Pharmaceuticals, Inc.
Application/Supplement Number	NDA 203752
Type of Application	Original
Indication(s)	For the treatment of moderate to severe vasomotor symptoms due to menopause
Established Pharmacologic Class[1]	Estrogen
Office/Division	ODE III/DRUP
Division Project Manager	Samantha Bell
Date FDA Received Application	December 29, 2011
Goal Date	October 29, 2012
Date PI Received by SEALD	October 25, 2012
SEALD Addendum Review Date	October 29, 2012
SEALD Labeling Team Leader	Eric Brodsky

PI = prescribing information

[1] The established pharmacologic class (EPC) that appears in the final draft PI.

The Study Endpoints and Labeling Development (SEALD) team performed a Selected Requirements of Prescribing Information (SRPI) review of the end-of-cycle, final agreed-upon Minivelle prescribing information (PI) on October 26, 2012. The review noted several format items that should be corrected prior to approval of the Minivelle PI.

This addendum review amends one of the SRPI items from the October 26, 2012 review (Item #15). Therefore, Item #15 (length of the Boxed Warning in Highlights) does not need to be corrected prior to application approval.

Guide to the SRPI Checklist: For each SRPI item, one of the following 3 response options is selected:

- **NO:** The PI **does not meet** the requirement for this item **(deficiency)**.
- **YES:** The PI **meets** the requirement for this item **(not a deficiency)**.
- **N/A** (not applicable): This item does not apply to the specific PI under review.

Highlights (HL)

HIGHLIGHTS DETAILS

Boxed Warning

15. Must be limited in length to 20 lines (this does not include the heading and statement "***See full prescribing information for complete boxed warning.***")

YES

Comment: *The length of the Boxed Warning in Highlights is 22 lines and is greater than the 20 line limit. However, the length of the Boxed Warning in Highlights in the Minivelle PI is acceptable at this time (there is no format deficiency).*

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

/s/

ERIC R BRODSKY
10/29/2012

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Labeling Memo

Date:	October 26, 2012
Reviewer:	Walter Fava, RPh, MSEd, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader:	Zachary Oleszczuk, PharmD, Team Leader Division of Medication Error Prevention and Analysis
Drug Name:	Minivelle (Estradiol Transdermal System) [redacted] (b) (4) 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, 0.1 mg/day
Application Type/Number:	NDA 203752
Applicant/Sponsor:	Noven Pharmaceuticals, Inc.
OSE RCM #:	2012-134

*** This document contains proprietary and confidential information that should not be released to the public.***

1 INTRODUCTION

This memo responds to a request from the Division of Reproductive and Urologic Products (DRUP) for a review of the revised carton labeling and container labels for Minivelle (Estradiol Transdermal System). DMEPA's initial review comments for the proposed labels and labeling submitted on April 27, 2012, were communicated to the Division on August 15, 2012, via e-mail. Some of DMEPA's review comments were included in an Advice Letter sent to the Applicant on September 24, 2012 (See Appendix A). The Applicant responded to the recommendations in the Advice Letter and submitted revised carton labeling and container labels on October 15, 2012. DMEPA reviewed the revised carton labeling and container labels and provided comments to the Division via e-mail on October 24, 2012. In response to those comments, the Applicant sent representative revised carton labeling and container labels via e-mail on October 26, 2012.

2 MATERIAL REVIEWED

DMEPA reviewed the representative revised Minivelle 0.5 mg/day carton labeling and pouch labels received via e-mail on October 26, 2012 (see Appendix B).

3 CONCLUSIONS AND RECOMMENDATIONS

Review of the revised representative carton labeling and pouch labels show that the Applicant accepted DMEPA's recommendations and we find the representative revisions acceptable for implementation for each strength. We have no additional recommendations at this time.

Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications on this review, please contact the OSE Regulatory Project Manager, Marcus Cato at 301-796-3903.

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