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APPLICATION NUMBER:
203752Orig1s000

PROPRIETARY NAME REVIEW(S)

**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**

Proprietary Name Review

Date: August 7, 2012

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Drug Name(s) and Strength(s): Minivelle (Estradiol) Transdermal System
(b) (4), 0.0375 mg, 0.05 mg, 0.075 mg, 0.1 mg

Application Type/Number: NDA 203752

Applicant/Sponsor: Noven Pharmaceuticals

OSE RCM #: 2012-1147

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Minivelle, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The Applicant originally submitted the proposed name, (b) (4) which DMEPA denied and notified the Applicant in a letter dated, April 5, 2012.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 11, 2012 proprietary name submission.

- Active Ingredient: Estradiol
- Indication of Use: Moderate to severe vasomotor symptoms due to menopause
- Route of administration: Topical
- Dosage form: Transdermal Delivery System
- Strength: (b) (4) 0.0375 mg, 0.05 mg, 0.075 mg, 0.1 mg
- Dose: One patch applied twice a week
- How Supplied and Container/Closure System: Carton containing 8 individually pouch sealed transdermal systems
- Storage: Room temperature 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).

2. RESULTS

The following sections provide the information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Reproductive and Urologic Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the safety evaluation of the proposed name.

2.2.1 *United States Adopted Names (USAN) SEARCH*

On June 29, 2012 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

This proprietary name is comprised of a single word that contains the letter string, ‘Mini’ which makes reference to the size of the transdermal system relative to other similar transdermal systems in this therapeutic class which are currently marketed (i.e. Vivelle and Vivelle Dot). The name also contains the letter string, ‘velle’, which is used in proprietary names for similar products.

2.2.4 FDA Name Simulation Studies

Thirty-three practitioners participated in DMEPA’s prescription studies. The interpretations did or did not overlap with or appear or sound similar to any currently marketed products. Ten participants responded correctly. The majority misinterpretations stemmed from participants in the outpatient study responding with ‘Minirelle’ (n = 6). Other misinterpretations included ‘Minnelle’ (n = 5), ‘Minival’ (n = 4), ‘Mini-Val’ (n=1), and ‘Minivalle’ (n=1). DMEPA noted that the incorrect responses, ‘Minival’, ‘Mini-Val’, and ‘Minivalle’, are phonetically and orthographically similar to an over the counter product, (b) (4) and the prescription product, Menaval-20. However, both (b) (4) and Menaval-20 were already identified by DMEPA and despite the phonetic and orthographic similarity, were found to have differentiating product characteristics which will minimize the chance of confusion that could lead to medication errors. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, May 30, 2012 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Minivelle. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Minivelle identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

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