

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**22-057**

**OTHER REVIEW(S)**

**MEMORANDUM**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

**DATE:** February 8, 2007

**TO:** Scott Monroe, M.D., Acting Director  
Division of Reproductive and Urologic Products

**VIA:** John Kim, Regulatory Project Manager  
Division of Reproductive and Urologic Products

**FROM:** Jeanine Best, M.S.N., R.N., P.N.P.  
Patient Product Information Specialist  
Division of Surveillance, Research, and Communication Support

**THROUGH:** Toni Piazza-Hepp, Pharm. D., Deputy Director  
Division of Surveillance, Research, and Communication Support

**SUBJECT:** DSRCs Review of Patient Labeling for Endometrin (progesterone effervescent vaginal tablet, 100mg), NDA 22-057

**Background and Summary**

An NDA was submitted August 21, 2006, for Endometrin (progesterone effervescent vaginal tablet, 100mg), NDA 22-057. Submitted labeling includes patient labeling in the form of a patient package insert (PPI).

**Comments and/or Recommendations**

1. See the attached PPI (marked and clean copies) with our suggested revisions. We have simplified the wording, made it consistent with the Full Prescribing Information (FPI), included progesterone-class risk information, removed unnecessary information, and put it in a Medication Guide question and answer-type format as described in 21 CFR 208.20. Although not required for Patient Information, we recommend that the Medication Guide format be used for Endometrin. Research and experience support the communication effectiveness of the Medication Guide format. All of our recommended changes are consistent with current research to improve risk communication to a broad audience of varying educational backgrounds including those with lower literacy.
2. Our revisions lowered the reading level from a grade level of 9.4 to 8.3 (Flesh-Kincaid). All patient information should be written at a 6<sup>th</sup> to 8<sup>th</sup> grade reading level to enhance comprehension.
3. The FPI does not contain Patient Counseling Information. Refer to 201.57 (18) *Patient Counseling Information*. The patient labeling does not replace this section. The Patient

Counseling Information section is written for prescribers and should contain the necessary counseling information for prescribers to pass on to their patients for safe and effective use.

4. Comments to the review division are ***bolded, underlined and italicized*** in the attached document. Please call us if you have any questions.

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5 Page(s) Withheld

       Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

       Draft Labeling (b5)

       Deliberative Process (b5)

Withheld Track Number: Other Reviews Section- 1

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/s/

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Jeanine Best  
2/8/2007 03:02:39 PM  
DRUG SAFETY OFFICE REVIEWER

Toni Piazza Hepp  
2/8/2007 04:57:37 PM  
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