Date of This Review: July 9, 2020
Application Type and Number: NDA 214846
Product Name and Strength: Myfembree (relugolix/estradiol/norethindrone acetate) tablet
40 mg/1 mg/0.5 mg
Product Type: Multiple Ingredient Product
Rx or OTC: Prescription (Rx)
Applicant/Sponsor Name: Myovant Sciences GmbH (Myovant)
Panorama #: 2020-40358824
DMEPA Safety Evaluator: Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader: Briana Rider, PharmD, CPPS
1 INTRODUCTION
This memorandum is to reassess the proposed proprietary name, Myfembree, which was found conditionally acceptable under IND 131161 on March 2, 2020. Myfembree was developed under IND 131160 for treatment of heavy menstrual bleeding associated with uterine fibroids. On June 2, 2020, Myovant submitted the name, Myfembree, for review under NDA 214846 for treatment of heavy menstrual bleeding associated with uterine fibroids. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT
The Office of Prescription Drug Promotion (OPDP) determined that Myfembree would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Urology, Obstetrics, and Gynecology (DUOG) concurred with the findings of OPDP’s assessment for Myfembree.

2.2 SAFETY ASSESSMENT
For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The July 1, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Myfembree.

2.3 COMMUNICATION OF DMEPA’S ANALYSIS AT MIDPOINT OF REVIEW
We communicated our findings to the Division of Urology, Obstetrics, and Gynecology (DUOG) via e-mail on July 1, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Urology, Obstetrics, and Gynecology (DUOG) on July 8, 2020, they stated no additional concerns with the proposed proprietary name, Myfembree.

3 CONCLUSION
Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Myfembree, is acceptable.

References:

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO MYOVANT SCIENCES GMBH

We have completed our review of the proposed proprietary name, Myfembree, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on June 2, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.
4 REFERENCE

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)
   USAN Stems List contains all the recognized USAN stems.
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DENISE V BAUGH
07/09/2020 09:37:05 AM

BRIANA B RIDER
07/09/2020 09:42:36 AM