CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-788

PROPRIETARY NAME REVIEW(S)

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

PROJECT #:	04-0106-1
DATE OF REVIEW:	March 3, 2005
TO:	Daniel Shames, MD Director, Division of Reproductive and Urologic Drug Products (HFD-580)
FROM:	Nora Roselle, PharmD Safety Evaluator, Division of Medication Errors and Technical Support (HFD-420)
THROUGH:	Alina Mahmud, RPh, MS, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Errors and Technical Support, Office of Drug Safety
SUBJECT:	**FINAL PROPRIETARY NAME REVIEW** **Drug:** Bijuva (Synthetic Conjugated Estrogen, A) Vaginal Cream, 0.625 mg per gram **NDA#:** 21-788 **Sponsor:** Duramed Pharmaceuticals, Inc. Subsidiary of Barr Pharmaceuticals, Inc.

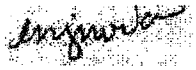
This consult is in response to a February 10, 2005, request from your Division for a re-review of the proprietary name, Bijuva.

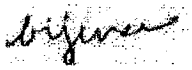
The sponsor currently markets Synthetic Conjugated Estrogen, A in a tablet dosage form under the proprietary name, Cenestin. In addition to this, the sponsor is seeking approval to market the same active ingredient as a vaginal cream dosage form under the proprietary name Bijuva. Although not discussed in our original review, DMETS questions why the sponsor is seeking a dual tradename for a product which could be effectively marketed under the current name, Cenestin. From the information provided we believe that the product is the vaginal cream formulation of the already marketed Cenestin tablets. DMETS is concerned that two health care professionals (for example, a general practitioner and a gynecologist) may prescribe the same active ingredient (with different proprietary names) to a single patient, thereby exposing the patient to an increased dose of the medication. According to the information provided, we believe that this situation is comparable to the Premarin product line, where Premarin tablets and Premarin vaginal cream are both effectively managed under a single proprietary name. We believe the product would be best marketed under the already recognized product name, Cenestin. DMETS met with the Division of Reproductive and Urologic Drug Products, and the Division has agreed to provide our comments to the sponsor.

With respect to the proposed proprietary name, Bijuva, it was previously found unacceptable by DMETS on August 9, 2004 (ODS Consult # 04-0106) due to potential for confusion with the marketed drug Enjuvia. The sponsor proposed an alternate name, ——— . DMETS had no objections to the use of the alternate name. However, the review division decided against DMETS recommendation and informed the sponsor that using Bijuva is acceptable. Despite the Division's decision, DMETS remains concerned with the potential for confusion with Bijuva and the name Enjuvia identified in our original review. b(4)

Enjuvia and Bijuva share overlapping product characteristics such as active ingredient (synthetic conjugated estrogen), numerical strength (0.625 mg vs. 0.625 mg/gram), indication for use (menopausal symptoms), frequency of administration (both may be given daily), and patient and prescriber population. Differences between the two drugs include route of administration (oral vs. vaginal) and dosage form (tablet vs. cream). It is possible that a prescription written for "Enjuvia 0.625 mg, use as directed" may be misinterpreted as

"Bijuva 0.625 mg/g, use as directed" if the handwriting for the two drug names is very similar. DMETS acknowledges that most prescriptions for Bijuva will be written without a strength. However, since Bijuva and Enjuvia share a strength of 0.625 mg, it is possible that a prescription for Enjuvia 0.625 mg to be misinterpreted as Bijuva 0.625 mg/g. Furthermore, the presence of the units of measure (mg/g vs. g) is not noticeably differentiating. While we recognize that the names look most similar when written in all lowercase cursive letters, there is no data to show that all prescriptions are written beginning with an uppercase letter. Therefore it is possible that a prescription drug name may be written in all lowercase letters as shown in the example below. Overall, DMETS believes that there is potential for confusion between Bijuva and Enjuvia due to the overlapping product characteristics and orthographic similarities.





Since the original review, DMETS expert-panel identified one additional proprietary name, Boniva, as having the potential for confusion with Bijuva. However, after further review, DMETS determined that Boniva does not possess strong look- or sound-alike similarity with the proposed name, Bijuva.

Additionally, in review of the insert labeling provided with this request, DMETS has identified the following area of possible improvement, which may minimize potential user error.

DOSAGE AND ADMINISTRATION Section

This section is confusing with regard to the usual dosage. In order to avoid confusion with dosing we recommend re-wording the Usual Dosage statement to read "One applicatorful (2 grams) intravaginally daily for one week followed by one applicatorful (2 grams) intravaginally twice a week."

In summary, DMETS has concerns with the potential dual tradename which would result from the use of the name Bijuva. We believe the product would be best marketed under the already recognized product name, Cenestin. In addition, DMETS continues to find the use of the name, Bijuva, unacceptable from a look-alike perspective with the already marketed drug Enjuvia. This is considered a final decision. If the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document. DDMAC finds the proprietary name, Bijuva, acceptable from a promotional perspective. Additionally, we recommend implementation of the labeling revision noted above. If you have any questions or need clarification, please contact Sammie Beam at 301-827-3242.

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/s/

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