CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-813

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

MEMORANDUM

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

DATE: October 12, 2006

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

VIA: George Lyght, Senior Regulatory Project Manager
Division of Reproductive and Urologic Products

FROM: Sharon R. Mills, BSN, RN, CCRP
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 Bio-E-Ge (transdermal estradiol gel), NDA 21-813

Background and Summary

DSRCS received a consult request to review the patient labeling for this new NDA for a transdermal estrogen product.

See the attached Patient Package Insert (PPI) for our recommended revisions to the proposed PPI submitted for Bio-E-Gel (transdermal estradiol gel, NDA 21-813. The purpose of patient information leaflets is to enhance appropriate use and provide important risk information about medications. We have simplified the wording where possible to make it more patient-friendly, made it consistent with the Professional Information (PI) and removed unnecessary information. We followed the format detailed in the *"Guidance for Industry: Noncontraceptive Estrogen Drug Products for the Treament of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms-Recommneded Prescribing Information for Health Care Providers and Patient Labeling."*

These revisions are based on the proposed Professional Information (PI) submitted on January 25, 2006. Patient information should always be consistent with the prescribing information. All future relevant changes to the PI should also be reflected in the PPI.

Comments and Recommendations

1. The PPI needs to conform to the Guidance document referenced above. We have modified the PPI where needed to reflect this, for example in putting the section "What is the Most Important Information I Should Know About [ ] (An Estrogen Hormone)" in a box as detailed in the beginning of the Guidance.

   The "*Patient Instructions for Use*" have been moved to the end of the PPI. Placing the instructions under the section "How should I use] breaks up the important safety information. This may interfere

with patients' attention to and understanding of the essential safety message of the PPI.

Comments to the review division are ***bolded, underlined and italicized***. Attached to this memo, we are providing to the review division a marked-up and clean copy of the revised PPI in Word. We recommend using the clean copy as the working document.

Please call us if you have any questions.

17 page(s) of draft labeling has been removed from this portion of the review.

Administrative + Correspondence Documents:
DSRCS Review (10/12/06)

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

/s/

Sharon Mills
10/12/2006 04:05:27 PM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
10/12/2006 04:18:21 PM
CSO
Jodi Duckhorn for Toni Piazza-Hepp