



NDA 020375/S-045  
NDA 020375/S-046

## SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.  
Attention: Resmi John, MD  
Associate Director, Regulatory Affairs  
100 Bayer Blvd.  
P. O Box 915  
Whippany, NJ 07981

Dear Dr. John:

Please refer to your supplemental new drug applications (sNDA's) dated and received April 12, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Climara/Menostar (estradiol transdermal system).

These "Changes Being Effected" sNDAs provide for the following change in container label and carton labeling: addition of recommended dose frequency .

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 020375/S-045 and S-046.**" Approval of this submission by FDA is not required before the labeling is used.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for

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the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Shiley, Regulatory Project Manager, at (301)796-2117.

Sincerely,

*{See appended electronic signature page}*

Christine P. Nguyen, M.D.  
Director  
Division of Urology, Obstetrics, and Gynecology  
Office of Rare Diseases, Pediatrics, Urological,  
and Reproductive Medicine  
Center for Drug Evaluation and Research

ENCLOSURE: Carton and Container Labeling

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**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.**  
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/s/  
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CHRISTINE P NGUYEN  
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