NDA 020538/S-040

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Sneha Desai
Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936

Dear Ms. Desai:

Please refer to your supplemental new drug applications (sNDA) dated and received April 1, 2021,submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vivelle-Dot (estradiol transdermal system).

This "Changes Being Effected" sNDA provides for the following changes in container label and carton labeling:

1. addition of recommended frequency of administration (i.e. twice weekly)
2. associated revision of the component code number for each label

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 020538/S-040."** 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 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

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/

CHRISTINE P NGUYEN
09/01/2021 03:37:29 PM