ANDA 204379

ANDA APPROVAL

Zydus Pharmaceuticals USA, Inc.
U.S. Agent for Zydus Noveltech, Inc.
73-B Route 31 North
Pennington, NJ 08534
Attention: Srinivas Gurram
Senior Vice President, Head of RA and CQA Lead - Americas

Dear Srinivas Gurram:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 26, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Estradiol Transdermal System USP, 0.014 mg/day.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on June 2, 2022, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Estradiol Transdermal System USP, 0.014 mg/day to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Menostar Transdermal System, 0.014 mg/day, of Bayer HealthCare Pharmaceuticals, Inc.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

John Ibrahim

Digitally signed by John Ibrahim
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