DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022247/S-002

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
REQUIREMENT**

Wyeth Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer, Inc.
Attention: Birming Wong
Director, Worldwide Safety & Regulatory
235 East 42nd Street
New York, NY 10017

Dear Ms. Wong:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 25, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Duavee (conjugated estrogens/bazedoxifene) tablets.

We acknowledge receipt of your amendment dated September 23, 2015.

This "Prior Approval" supplemental new drug application proposes revisions to the Prescribing Information to include results from Post-Marketing Study B2311065, which was a pharmacokinetic study that evaluated the effect of a strong CYP3A4 inhibitor and body weight on the exposure of conjugated estrogens and bazedoxifene in postmenopausal women.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated, March 25, 2015, containing the final report for the following postmarketing requirement listed in the October 3, 2013 approval letter.

2083-1 Pharmacokinetic trial evaluating the effect of a strong CYP3A4 inhibitor and body weight on the exposure of conjugated estrogens and bazedoxifene titled "A Phase 1, Open-Label, Two-Period, Fixed-Sequence Study to Estimate the Effects of Steady State Administration of a Strong CYP3A4 Inhibitor on the Single-Dose Pharmacokinetics of Conjugated Estrogens/Bazedoxifene in Non-obese (Body Mass Index <30 kg/m2) and Obese (Body Mass Index ≥ 30 kg/m2) Postmenopausal Women."

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our October 3, 2013, letter.

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 Samantha Bell, Regulatory Project Manager, at (301) 796-9687.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, M.D.
Deputy Director for Safety
Division of Bone, Reproductive, and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

CHRISTINE P NGUYEN
09/25/2015