

NDA 017802/S-034
NDA 017948/S-046
NDA 018926/S-013
NDA 019190/S-049
NDA 019192/S-048

SUPPLEMENT APPROVALS

Wyeth Pharmaceuticals, LLC
Attention: Michelle Patel, R.Ph.
Manager, Pfizer Essential Health Global Regulatory Affairs Brands
235 East 42nd Street
New York, NY 10017

Dear Dr. Patel:

Please refer to your supplemental new drug applications (sNDAs) dated and received November 29, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 017802/S-034 Lo/Ovral® (norgestrel and ethinyl estradiol) Tablets
NDA 017948/S-046 Norminest Fe (ethinyl estradiol, ferrous fumarate,
norethindrone)
Tablets
NDA 018926/S-013 Norquest Fe (ethinyl estradiol; ferrous fumarate;
norethindrone) Tablets
NDA 019190/S-049 Triphasil®- 21 (levonorgestrel and ethinyl estradiol) Tablets
NDA 019192/S-048 Triphasil®- 28 (levonorgestrel and ethinyl estradiol) Tablets

These Prior Approval supplemental new drug applications provide for changes to the Prescribing Information to align the text for Hereditary Angioedema under the PRECAUTIONS section and Mechanism of Action under the CLINICAL PHARMACOLOGY section to the December 2017 Draft Guidance for Industry, Labeling for Combined Hormonal Contraceptives.

APPROVAL & LABELING

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient 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 *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 (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.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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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 Jennifer Dao, Regulatory Project Manager, at (301) 796-8189.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

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/

AUDREY L GASSMAN
05/08/2019 10:07:29 PM