DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021098/S-023
NDA 022532/S-006
NDA 022574/S-006
NDA 021676/S-014

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Sharon Brown
Director, Global Regulatory Affairs
P.O. Box 0915
100 Bayer Blvd.
Whippany, NJ 07981-0915

Dear Ms. Brown:

Please refer to your Supplemental New Drug Applications (sNDAs) under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Supplement	Drug Name	Dated and Received Date
021098	023	Yasmin (drospirenone/ethinyl estradiol) Tablets	May 23, 2014
021676	014	YAZ (drospirenone/ethinyl estradiol) Tablets	May 21, 2014
022532	006	Beyaz (drospirenone/ethinyl estradiol/levomefolate calcium) Tablets	May 23, 2014
022574	006	Safyral (drospirenone/ethinyl estradiol/levomefolate calcium) Tablets	May 23, 2014

We also refer to your submissions received July 7, and December 8, 2014; April 20 and May 20, 2015.

These "Prior Approval" supplemental new drug applications propose to update the Warnings and Precautions, Drug Interactions and Pharmacokinetic sections of the physician labeling and the "What else should I know about taking [NAME]" section of the patient labeling for Yasmin, YAZ, Beyaz, and Safyral, by providing additional information about drug-drug interactions.

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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, text for the patient package insert, Medication Guide), 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 applications, 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 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

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

/s/

AUDREY L GASSMAN
06/01/2015