DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021998/S-002

SUPPLEMENT APPROVAL

Teva Branded Pharmaceutical Products R&D, Inc.
Attention: Amy Hummel, M.S.
Associate Director, Regulatory Affairs
41 Moores Road, P.O. Box 4011
Frazer, PA 19355

Dear Ms. Hummel:

Please refer to your supplemental new drug application dated and received February 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plan B One-Step® (levonorgestrel) tablet, 1.5 mg.

We also refer to your submissions dated March 9, 2012, June 11, 2012, June 27, 2012, March 13, 2013, April 4, 2013, and April 15, 2013. The March 9, 2012, submission constituted a complete response to our December 7, 2011 action letter. This "Prior Approval" supplemental new drug application provides for making Plan B One-Step available over the counter to women of childbearing potential aged 15 years and over who are in need of emergency contraception.

We note that the approved labeling contains the language "not for sale to those under 15 years of age * proof of age required * not for sale where age cannot be verified." Therefore, you must have appropriate mechanisms in place to ensure that the age of the purchaser is verified at the point of purchase.

We also note and agree with your plan to audit retail outlets, described in your submission dated March 13, 2013, that is designed to assure consumer compliance with the approved labeling. We request that you submit a report of your findings for review by the agency upon completion.

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 agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as it is available, but no more than 30 days after it is printed. The final printed labeling (FPL) must be identical to the enclosed labeling:

- immediate container labels (1-count blister) submitted on October 21, 2011,
- clinic and retail outer carton labels submitted on April 15, 2013,
- clamshell label front and back cards (Product identification cards) submitted on April 15, 2013, and
- consumer information leaflet submitted on December 7, 2011

and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021998/S-002**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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.

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 Doris J. Bates, Ph.D., Senior Regulatory Project Manager, at (301) 796-1040.

Sincerely,

{See appended electronic signature page}

Shaw T. Chen, M.D., Ph.D.,
Director (Acting)
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling
Product Identification Cards
Consumer Information Leaflet

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

/s/

SHAW T CHEN
04/30/2013