DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021998/S-003

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 (sNDA) dated and received June 17, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plan B One-Step® (levonorgestrel) tablet, 1.5 mg.

The supplemental NDA was submitted in response to our June 10, 2013 supplement request letter, in which we stated our intent to comply with the April 5, 2013 court order (*Tummino, et al. v. Hamburg, et al.,* No. 12-CV-763 (ERK) (U.S. District Court, Eastern District of New York) requiring FDA to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days."

This sNDA proposes the following changes: revisions in labeling to make Plan B One-Step available as a nonprescription product without point-of-sale or age restrictions. We have completed our review of this application. 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:

- 1-count outer carton retail (trade) label
- 1-count outer carton retail (trade) (for clamshell) label
- 1-count outer carton clinic label
- 1-count outer carton label-over-label sticker (front)
- 1-count outer carton label-over-label sticker (back),

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

In order to maintain a complete record of the labeling approved as part of this supplement, please also submit FPL for the following two labeling components, which were not revised in this supplement:

- 1-count immediate container (blister) label
- Consumer Information Leaflet

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-003." Approval of this submission by FDA is not required before the labeling is used.

Please remove the statement "New! Now Available Over the Counter" from the labeling after six months of marketing.

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.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

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 supplemental 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

ENCLOSURES:
Approved Labeling

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
06/20/2013