NDA 021998/S-005

SUPPLEMENT APPROVAL

Foundation Consumer Healthcare, LLC
(b) (4), (b) (6)

Dear Applicant:

Please refer to your supplemental new drug application (sNDA) dated and received June 15, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Plan B One-Step (levonorgestrel) tablet, 1.5 mg.

This "Prior Approval" supplemental new drug application provides for changes to the labeling that is related to mechanism of action in the Drug Facts label (DFL) and Consumer Information Leaflet (CIL).

APPROVAL & LABELING

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 enclosed agreed-upon labeling with minor editorial revisions listed below.

- Ensure that the statement of identity on the principal display panel of the clinic and trade cartons is bolded, per 21 CFR 201.61(c).

LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	**Date Submitted**
Outer carton label – trade	June 17, 2022
Outer carton label – trade (narrow)	June 17, 2022
Outer carton label – clinic	June 17, 2022
Consumer Information Leaflet	December 8, 2022

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021998/S-005**." 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 FDA.gov.[2] 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*. 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.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Sincerely,

{See appended electronic signature page}

(b) (6)

Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton Labeling
- Consumer Information Leaflet

[1] 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.
[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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/

(b) (6)

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