NDA 017031/S-041

SUPPLEMENT APPROVAL

Laboratoire HRA Pharma
Attention: Ann Robbins, PhD
HRA Pharma Regulatory Agent
President, Ann Robbins LLC
6430 Sun Eagle Lane, Unit 301
Bradenton, FL 34210

Dear Dr. Robbins:

Please refer to your supplemental new drug application (sNDA) dated and received June 14, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Opill (norgestrel) tablet, 0.075mg.

We acknowledge receipt of your major amendment dated October 13, 2022, which extended the goal date by three months.

This "Prior Approval" supplemental new drug application provides for the full prescription-to-nonprescription switch of Opill (norgestrel) tablet, 0.075 mg.

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.

LABELING

Submit final printed labeling (FPL), 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 Draft Labeling	**Date Submitted**
Immediate Container (Blister Package) Label	June 20, 2023
Outer Carton for One 28-Count Blister Pack	June 20, 2023
Outer Carton for Two 28-Count Blister Packs	June 20, 2023

Outer Carton for Three 28-Count Blister Packs	June 20, 2023
Outer Carton for Six 28-Count Blister Packs	June 20, 2023
Consumer Information Leaflet	June 20, 2023
Reminder Card	June 20, 2023

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 017031/S-041**." Approval of this submission by FDA is not required before the labeling is used.

Note that 28-day blister packaging, with the required labeling on the blister packaging, is important for the safe and effective use of this product. Packaging changes will require a Prior Approval Supplement, and may require consumer behavior testing to support the changes.

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.

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

[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

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.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(C) to FDA on Form FDA 3542 within 30 days after the date of approval of this supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). Until you submit Form FDA 3542 (as required by 21 CFR 314.53(d)(2)(i)(C)) or until 30 days after the date of approval of this supplement (whichever comes first), FDA will carry over (i.e., continue to list) the patent information listed for this product in the prescription section of the Orange Book as of the date of approval of this supplement requesting to change the drug product from prescription use to over-the-counter use. If you do not submit Form FDA 3542 by the end of the 30-day period, the carried-over patent information will be removed from the Orange Book at the end of the 30-day period, unless information must remain listed in order to preserve a first applicant's eligibility for 180-day exclusivity, in which case the patent information would be identified with a patent *delist request* flag until the patent is removed from the Orange Book.

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 Anna Thai, Senior Regulatory Project Manager, at (301) 796-6533.

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Deputy Director
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

and

{See appended electronic signature page}

Christine P. Nguyen, MD
Deputy Director
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton, Container, Consumer Information Leaflet, and Reminder Card Labeling

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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/

CHRISTINE P NGUYEN
07/13/2023 07:33:36 AM

KAREN M MURRY
07/13/2023 07:36:32 AM