



NDA 017031 S-044

SUPPLEMENT APPROVAL

Laboratoire HRA Pharma
c/o Perrigo R&D Company
Attention: Valerie Gallagher
Vice President Regulatory Affairs
430 Monroe Ave NW
Grand Rapids, MI 49503

Dear Valerie Gallagher:

Please refer to your supplemental new drug application (sNDA) dated and received March 31, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Opill (norgestrel) tablet, 0.075 mg.

This “Prior Approval” supplemental new drug application provides for the addition of an alternative carton layout using a four-panel carton for the 1-month and 3-month supply configurations.

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
Outer carton for the 1 x 28-day supply	September 18, 2025
Outer carton for the 3 x 28-day supply	September 18, 2025

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-044.**” Approval of this submission by FDA is not required before the labeling is used. Also include the following as part of the FPL for your supplement in order to maintain a record of complete labeling:

- Immediate container (blister pack)
- Consumer Information Leaflet
- Reminder Card

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.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Anna Thai, Pharm.D.
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6113
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Anna Thai, Pharm.D.
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room:6113
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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,

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>

(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).

If you have any questions, contact Anna Thai, Senior Regulatory Project Manager, at Anna.Thai@fda.hhs.gov or 301-796-6533.

Sincerely,

{See appended electronic signature page}

Melanie Blank, M.D., M.S.
Deputy Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton Labeling

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/

MELANIE J BLANK
09/24/2025 12:38:18 PM