



NDA 022327/S-029

SUPPLEMENT APPROVAL

Perrigo Pharma International Designated Activity Company (PPI-DAC)
Attention: Jesse T. Evans
Regulatory Affairs Project Manager, ANDA/NDA
515 Eastern Ave.
Allegan, MI 49010

Dear Mr. Evans:

Please refer to your supplemental new drug application (sNDA) dated and received September 24, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevacid 24 HR (lansoprazole delayed release) capsules, 15 mg.

This “Prior Approval” supplemental new drug application provides for:

- Addition of the tips for managing heartburn to the outer labeling
- Removal of the package insert from the NDA
- Removal of labeling statements referencing a package insert within and outside of the DFL on the outer labeling
- Updates to the distributor, copyright, trademark, and phone number on the outer carton labeling
- Addition of the imprint “P24HR” on the capsule images on the outer carton labeling

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), 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 in the “Drug Facts” format (21 CFR 201.66), where applicable and be identical to the following labeling submitted on November 30, 2021:

1. 14-count outer carton
2. 28-count outer carton
3. 42-count outer carton

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 022327/S-029.**” Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future (e.g., individual immediate containers containing greater than 14-count, total package sizes greater than 42-count), a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use must be submitted. We encourage you to contact us about the content and format of such a supplement prior to submission.

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 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.

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>

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 Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container 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/

NUSHIN F TODD
03/01/2022 03:59:28 PM