NDA 208025/S-012

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Limited
c/o: ICON Clinical Research LLC (Authorized US Agent)
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
4130 Parklake Avenue, Suite 300
Raleigh, NC 27612

Dear Ms. Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received May 2, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for lansoprazole delayed-release orally disintegrating tablets, 15 mg.

This "Prior Approval" supplemental new drug application provides for:

- Revision of the Drugs Facts label to 1.) include a warning for Severe Cutaneous Adverse Reactions (SCARs) in accordance with FDA's CBE Supplement Request letter issued on March 7, 2022, and 2.) elevate cardiac warnings from the "***Ask a doctor before use***" subheading to the "***Do not use***" subheading.
- Changes related to the approval of NDA 022327/S-029 for Prevacid 24HR involving the removal of the package insert, addition of tips for managing heartburn to the outer cartons, and the removal of reference to a package insert.
- Updated labeling to include instructions to store the tablets in their original package.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the following:

Submitted Labeling	Date Submitted
14-Count inner carton	October 12, 2022
14-Count outer carton - Main	October 12, 2022
14-Count outer carton - “Orally Disintegrating Tablets” stated in proximity to tablet image	October 12, 2022
14-Count outer carton - Child resistant	October 12, 2022
28-Count outer carton - Main	October 12, 2022
28-Count outer carton - “Orally Disintegrating Tablets” stated in proximity to tablet image	October 12, 2022
28-Count outer carton – Value 2 Pack	October 12, 2022
28-Count outer carton - Child resistant	October 12, 2022
28-Count outer carton Bonus - “Buy One 14 Count, Get One 14 Count Free!”	October 12, 2022
28-Count outer carton Bonus - “100% More Free! 14 Free Tablets!”	October 12, 2022
28-Count outer carton Bonus - “Bonus Size! 14 Tablets Free”	October 12, 2022
28-Count outer carton Bonus - “Bonus Size! 14 Free”	October 12, 2022
28-Count outer carton Bonus - “Bonus! + 14 Free”	October 12, 2022
28-Count outer carton Bonus - “Bonus! 14 Tablets FREE”	October 12, 2022
42-Count outer carton - Main	October 12, 2022
42-Count outer carton - “Orally Disintegrating Tablets” stated in proximity to tablet image	October 12, 2022
42-Count outer carton – Value 3 Pack	October 12, 2022
42-Count outer carton - Child resistant	October 12, 2022
42-Count outer carton Bonus - “Bonus Pack: 28 + 14 Free”	October 12, 2022
42-Count outer carton Bonus - “Bonus Size! 14 Tablets Free”	October 12, 2022
42-Count outer carton Bonus - “Bonus Size! 14 Free”	October 12, 2022
42-Count outer carton Bonus - “Bonus! + 14 Free”	October 12, 2022
42-Count outer carton Bonus - “Bonus! 14 Tablets FREE”	October 12, 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 208025/S-012**.” Approval of this submission by FDA is not required before the labeling is used.

We also recommend a minor formatting change in the FPL to include a period after the first statement in the updated SCARs warning i.e., “do not use if you are allergic to lansoprazole.”

[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.

If you are interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14-count, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of use.

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).

If you have any questions, call Cynthia Kim, PharmD, Senior Regulatory Project Manager at 301-796-0879.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

- Carton Labeling

[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/

NUSHIN F TODD
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