



NDA 208025/S-018

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd.
c/o Edenbridge Pharmaceuticals, LLC (US Authorized Agent)
Attention: Robert S. Vincent
Associate Director, Regulatory Affairs
1 Upper Pond Road, Suite D250
Parsippany, NJ 07054

Dear Robert Vincent:

Please refer to your supplemental new drug application (sNDA) dated and received, July 28, 2025, and your amendments, submitted under section 505(b) 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 the addition of the “DISSOLVE TABS” descriptor above the statement of identity on the principal display panel, as well as editorial labeling changes.

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 |
|--|-----------------------|
| 7-count blister foil | January 26, 2026 |
| 14-count inner carton | January 26, 2026 |
| 14-count outer carton – Main | January 26, 2026 |
| 14-count outer carton with “Child-resistant” statement | January 26, 2026 |
| 14-count outer carton – tablet image text | January 26, 2026 |
| 28-count outer carton – Main | January 26, 2026 |
| 28-count outer carton with “Child-resistant” statement | January 26, 2026 |

| | |
|---|------------------|
| 28-count outer carton – tablet image text | January 26, 2026 |
| 28-count outer carton with “Buy One 14 Count, Get One 14 Count Free!” statement | January 26, 2026 |
| 28-count outer carton with “100% More Free! 14 Free Tablets!” statement | January 26, 2026 |
| 28-count outer carton with “Bonus Size! 14 Tablets Free” statement | January 26, 2026 |
| 28-count outer carton with “Bonus Size! 14 Free” statement | January 26, 2026 |
| 28-count outer carton with “Bonus! + 14 Free” statement | January 26, 2026 |
| 28-count outer carton with “Bonus! 14 Tablets FREE” statement | January 26, 2026 |
| 28-count outer carton with “Value 2 Pack” statement | January 26, 2026 |
| 42-count outer carton – Main | January 26, 2026 |
| 42-count outer carton with “Child-resistant” statement | January 26, 2026 |
| 42-count outer carton – tablet image text | January 26, 2026 |
| 42-count outer carton with “Bonus Pack: 28 + 14 Free” statement | January 26, 2026 |
| 42-count outer carton with “Bonus Size! 14 Tablets Free” statement | January 26, 2026 |
| 42-count outer carton with “Bonus Size! 14 Free” statement | January 26, 2026 |
| 42-count outer carton with “Bonus! + 14 Free” statement | January 26, 2026 |
| 42-count outer carton with “Bonus! 14 Tablets FREE” statement | January 26, 2026 |
| 42-count outer carton with “Value 3 Pack” statement | January 26, 2026 |

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-018.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you of the conditions of approval for this product which states, “If you intend to market other package configurations in the future (e.g., individual containers

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>.

containing greater than 14-count, total package sizes greater than 42-count), we will expect submission of a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of use.” 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.

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 Cynthia Kim, PharmD, BCPS, Senior Regulatory Project Manager, at Cynthia.Kim@fda.hhs.gov or 301-796-0879.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Carton and Container Labeling

² <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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
03/11/2026 11:13:27 AM