

NDA 209400/S-021

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Limited
 c/o: ICON Clinical Research LLC (Authorized US Agent)
 Attention: Amy Kneifel, RAC
 Director, Regulatory Affairs
 731 Arbor Way, Suite 100
 Blue Bell, PA 19422

Dear Amy Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received, July 22, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed release orally disintegrating tablet, 20 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 28, 2026
2-count physician sample with “FDA Approved” statement	January 28, 2026
14-count inner carton	January 28, 2026
14-count outer carton – Main	January 28, 2026
14-count outer carton with “FDA Approved” statement	January 28, 2026
14-count outer carton with “Child-resistant” statement	January 28, 2026
14-count outer carton – tablet image text	January 28, 2026

28-count outer carton – Main	January 28, 2026
28-count outer carton with “FDA Approved” statement	January 28, 2026
28-count outer carton with “Child-resistant” statement	January 28, 2026
28-count outer carton – tablet image text	January 28, 2026
28-count outer carton with “Buy One 14 Count, Get One 14 Count Free!” statement	January 28, 2026
28-count outer carton with “100% More Free! 14 Free Tablets!” statement	January 28, 2026
28-count outer carton with “Bonus Size! 14 Tablets Free” statement	January 28, 2026
28-count outer carton with “Bonus Size! 14 Free” statement	January 28, 2026
28-count outer carton with “Bonus! + 14 Free” statement	January 28, 2026
28-count outer carton with “Bonus! 14 Tablets FREE” statement	January 28, 2026
28-count outer carton with “Value 2 Pack” statement	January 28, 2026
42-count outer carton – Main	January 28, 2026
42-count outer carton with “FDA Approved” statement	January 28, 2026
42-count outer carton with “Child-resistant” statement	January 28, 2026
42-count outer carton – tablet image text	January 28, 2026
42-count outer carton with “Bonus Pack: 28 + 14 Free” statement	January 28, 2026
42-count outer carton with “Bonus Size! 14 Tablets Free” statement	January 28, 2026
42-count outer carton with “Bonus Size! 14 Free” statement	January 28, 2026
42-count outer carton with “Bonus! + 14 Free” statement	January 28, 2026
42-count outer carton with “Bonus! 14 Tablets FREE” statement	January 28, 2026
42-count outer carton with “Value 3 Pack” statement	January 28, 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 209400/S-021.**” 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 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, call Cynthia Kim, PharmD, BCPS, Senior Regulatory Project Manager, at Cynthia.Kim@fda.hhs.gov or 301-796-0879.

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>

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

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 09:34:59 AM