NDA 022032/S-070

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, June 5, 2025, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

This "Prior Approval" sNDA provides for an alternative packaging configuration for the Wildberry Mint and Cool Mint flavored products' 28-count and 42-count (blister) outer cartons consisting of two or three 14-tablet blisters, respectively, without the 14-count inner cartons. Labeling changes to the immediate container (blister) in this alternative packaging include:

- Addition of the following statements to the top of the blister: "KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION. READ WARNINGS AND DIRECTIONS ON CARTON BEFORE USE."
- Addition of the following text to the main blister cell: "This single 14-tablets blister package contains one 14-day course of treatment."
- Addition of the following text to each tablet-containing blister cell: "Take 1 tablet a day for 14 days."
- Changes in text location:
  - The manufacturer's name and address were moved from each blister cell to the bottom part of the blister.
  - Instructions for use, "Swallow whole. Do not chew, crush, or suck tablets" were moved from the main blister cell to appear on each tablet-containing blister.

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
Wildberry Mint flavored tablets 14-count immediate container (blister foil)	September 18, 2025
Cool Mint flavored tablets 14-count immediate container (blister foil)	September 18, 2025

If you intend to market other package configurations in the future (e.g., bottles containing greater than 14 tablets, 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 limitations of use. We encourage you to contact us about the content and format of such a supplement prior to submission.

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 022032/S-070**." Approval of this submission by FDA is not required before the labeling is used.

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.

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

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

ENCLOSURE:

- 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
10/03/2025 04:32:33 PM