NDA 022032/S-065

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 400
Raleigh, NC 27612

Dear Amy Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received July 10, 2024, and your amendments, 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 28-count and 42-count (blister) outer cartons consisting of two and three 14-tablet blisters, respectively, without the 14-count inner cartons, and labeling changes to the immediate container (blister) including:

- 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 statement, "Take 1 tablet a day for 14 days" to each blister cell containing a tablet.

- Modification of the existing statement, "One 14-day course of treatment" to "THIS SINGLE 14-TABLETS BLISTER PACKAGE CONTAINS ONE 14-DAY COURSE OF TREATMENT."

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
Unflavored Tablets	
14-count immediate container (blister foil)	November 4, 2024

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-065**." 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., immediate containers containing more than 14-count, package sizes more than 42-count), a prior approval labeling 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.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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

If you have any questions, call Cynthia Kim, 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
Office of New Drugs

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
11/08/2024 10:02:48 AM