DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 209400/S-005

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd
c/o: Icon Clinical Research LLC (Authorized Agent)
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Drive
4401 Research Commons Bldg, Suite 300
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 29, 2018, 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" sNDA provides for the following labeling changes:

- Revisions to the Drug Facts labeling (DFL) "Ask a doctor or pharmacist before use if you are taking" section per the FDA's June 29, 2018 request letter.

- Additional changes to the principal display panel consistent with approved Prilosec OTC 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 agreed-upon labeling text.

If you request to market other package configurations in the future (e.g., packages 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.

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 identical to the following labels submitted below:

Submitted Labeling	Date(s) Submitted
14-count inner carton	October 2, 2018
2-count outer carton (professional sample)	January 21, 2019
14-count outer carton - *Main*	October 2, 2018
28-count outer carton – *Main*	October 2, 2018
42-count outer carton - *Main*	October 2, 2018
14-count outer carton with 'Orally Disintegrating Tablets' flag	October 2, 2018
28-count outer carton with 'Orally Disintegrating Tablets' flag	October 2, 2018
42-count outer carton with 'Orally Disintegrating Tablets' flag	October 2, 2018
14-count outer carton with 'Child-resistant' flag	October 2, 2018
28-count outer carton with 'Child-resistant' flag	October 2, 2018
42-count outer carton with 'Child-resistant' flag	October 2, 2018
14-count outer carton with 'FDA Approved' flag	October 2, 2018
28-count outer carton with 'FDA Approved' flag	October 2, 2018
42-count outer carton with 'FDA Approved' flag	October 2, 2018
28-count outer carton with 'Value 2 Pack' flag	October 2, 2018
42-count outer carton with 'Value 3 Pack' flag	October 2, 2018
28-count outer carton with 'Buy One 14 Count, Get One 14 Count Free!' flag	October 2, 2018
28-count outer carton with '100% More Free! 14 Free Tablets!' flag	October 2, 2018
28-count outer carton with 'Bonus Size! 14 Tablets Free' flag	October 2, 2018
28-count outer carton with 'Bonus Size! 14 Free' flag	October 2, 2018
28-count outer carton with 'Bonus! + 14 Free' flag	October 2, 2018
28-count outer carton with 'Bonus! 14 Tablets FREE' flag	October 2, 2018

42-count outer carton with 'Bonus Pack: 28 + 14 Free' flag	October 2, 2018
42-count outer carton with 'Bonus Size! 14 Tablets Free' flag	October 2, 2018
42-count outer carton with 'Bonus Size! 14 Free' flag	October 2, 2018
42-count outer carton with 'Bonus! + 14 Free' flag	October 2, 2018
42-count outer carton with 'Bonus! 14 Tablets FREE' flag	October 2, 2018
IRC associated with 14-count outer carton, Peel-off PDP	October 2, 2018
IRC associated with 28-count outer carton, Peel-off PDP	October 2, 2018
IRC associated with 42-count outer carton, Peel of PDP	October 2, 2018

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 209400/S-005**." 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. 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.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/u

cm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Container and Carton 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/

KAREN M MAHONEY
01/28/2019 11:50:03 AM