DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209400

NDA APPROVAL

NDA 209400
Dexcel Pharma Technologies Ltd.
Attention: Jeanne Novak, PhD (US Agent, CBR International Corp)
CEO and Principal Consultant
2905 Wilderness Place, Suite 202
Boulder, CO 80301

Dear Dr. Novak:

Please refer to your New Drug Application (NDA) dated and received September 6, 2016, 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 new drug application provides for the use of omeprazole delayed-release orally disintegrating tablet for the treatment of frequent heartburn (occurs 2 or more days a week).

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. We remind you to remove the "NEW DOSAGE FORM!" flag 6 months after introduction to the marketplace.

If you request to market other package configurations in the future (e.g., bottles containing greater than 14 capsules, 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 (see table below), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission date
2-count immediate container (blister)	June 2, 2017
2-count sample carton	June 2, 2017
7-count immediate container (blister)	September 6, 2016

14-count immediate container (blister)	September 6, 2016
14-count inner carton (blister)	June 2, 2017
14-count blister carton with "NEW DOSAGE FORM"	June 2, 2017
14-count blister carton with "FDA Approved"	June 2, 2017
28-count blister carton with "NEW DOSAGE FORM"	June 2, 2017
28-count blister carton with "FDA Approved"	June 2, 2017
42-count blister carton with "NEW DOSAGE FORM"	June 2, 2017
42-count blister carton with "FDA Approved"	June 2, 2017
14-count immediate container (bottle)	June 2, 2017
14-count bottle carton	June 2, 2017
28-count bottle carton	June 2, 2017
42-count bottle carton	June 2, 2017

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**." 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/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because there is evidence strongly suggesting that the drug product would be ineffective or unsafe in all pediatric age groups for over the counter use. We are waiving the pediatric study requirement for this application because the current position of the Agency is that heartburn in pediatric patients needs to be evaluated and treated by a physician.

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):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
07/05/2017