DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209400/S-001

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 September 19, 2017, 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 following:

- Addition of the "MELTech™ Melts in Your Mouth" logo to the principal display panel (PDP) of all cartons
- New bonus label flags ('Child-resistant'; 'Buy One 14 count, Get One 14 count Free!'; '100% More Free! 14 Free Tablets!'; 'Value 2 Pack'; 'Bonus Size! 14 Tablets Free'; 'Bonus Size! 14 Free'; 'Bonus! + 14 Free'; 'Bonus! 14 Tablets FREE'; 'Bonus Pack: 28 +14 Free'; and 'Value 3 Pack')
- Three instantly redeemable coupons
- Redesign of the principle display panel (e.g., repositioning of the NDC number and 'Melts in Your Mouth' flag, removal of yellow background on 'FDA Approved' flag)
- Minor editorial revisions to the manufacturer address
- Removal of all *bottle* immediate container and outer carton labels

We have completed our review of this application. 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. In addition, if you request 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.

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 to the following list of labels submitted on September 19, 2017, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

1. 2-count immediate container (blister)
2. 7-count immediate container (blister)
3. 14-count immediate container (blister)
4. 14-count blister inner carton
5. 2-count blister outer carton (sample)
6. 14-count blister outer carton
7. 28-count blister outer carton
8. 42-count blister outer carton
9. 14-count blister outer carton with 'Orally Disintegrating Tablets' flag
10. 28-count blister outer carton with 'Orally Disintegrating Tablets' flag
11. 42-count blister outer carton with 'Orally Disintegrating Tablets' flag
12. 14-count blister outer carton with 'Child-resistant' flag
13. 28-count blister outer carton with 'Child-resistant' flag
14. 42-count blister outer carton with 'Child-resistant' flag
15. 14-count blister outer carton with 'FDA Approved' flag
16. 28-count blister outer carton with 'FDA Approved' flag
17. 42-count blister outer carton with 'FDA Approved' flag
18. 28-count blister outer carton with 'Value 2 Pack' flag
19. 42-count blister outer carton with 'Value 3 Pack' flag
20. 28-count blister outer carton with 'Buy One 14 Count, Get One 14 Count Free!' flag
21. 28-count blister outer carton with '100% More Free! 14 Free Tablets!' flag
22. 28-count blister outer carton with 'Bonus Size! 14 Tablets Free' flag
23. 28-count blister outer carton with 'Bonus Size! 14 Free' flag
24. 28-count blister outer carton with 'Bonus! + 14 Free' flag
25. 28-count blister outer carton with 'Bonus! 14 Tablets FREE' flag
26. 42-count blister outer carton with 'Bonus Pack: 28 + 14 Free' flag
27. 42-count blister outer carton with 'Bonus Size! 14 Tablets Free' flag
28. 42-count blister outer carton with 'Bonus Size! 14 Free' flag
29. 42-count blister outer carton with 'Bonus! + 14 Free' flag
30. 42-count blister outer carton with 'Bonus! 14 Tablets FREE' flag
31. 14-count outer carton Instant Redeemable Coupon (IRC)
32. 28-count outer carton IRC
33. 42-count outer carton IRC

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-001**." 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".)

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
02/28/2018