DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22032/S-032

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd.
c/o ICON Clinical Research LLC
Attention: Ms. Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Drive
4401 Research Commons Building, Suite 300
P.O. Box 14353
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your Supplemental New Drug Application (sNDA) dated August 13, 2015, received August 13, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

This "Changes Being Effected" sNDA provides revisions to labeling to include drug-drug interactions with mycophenolate mofetil and methotrexate.

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.

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 wildberry mint 14-count blister and bottle immediate containers, 14-count inner blister carton, 14-, 28- and 42-count blister cartons, 14-, 28- and 42-count bottle cartons, "FDA Approved" flag for the 14-, 28- and 42-count blister and bottle cartons, "14 FREE" flag for the 28- and 42-count blister and bottle cartons, "Bonus! 14 Free" flag for the 28- and 42-count blister and bottle cartons, "Bonus pack! 14 Free" flag for the 28- and 42-count blister and bottle cartons, "28 + 14 FREE" flag for the 42-count blister and bottle cartons, "Triple Pack Three 14-day courses of treatment" flag for the 42-count blister and bottle cartons, "Value Pack! 3-14 Tablet Cartons" for the 42-count blister and bottle cartons, "3 Pack Three 14-day courses of treatment" for the 42-count blister and bottle cartons, and PDP peel-off Instant Rebate Coupons for the 14-, 28-, and 42-count blister and bottle cartons submitted August 13, 2015, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22032/S-032**." 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.

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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

VALERIE S PRATT
02/10/2016