DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22032/S-029

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd.
c/o Lachman Consultant Services, Inc.
Attention: Mary-Anne D'Esposito, M.S.
Director
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated December 12, 2014, received December 12, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Omeprazole Delayed Release tablets, 20 mg.

We acknowledge receipt of your amendment dated May 18, 2015. We also reference our October 31, 2014 CBE-0 supplement request letter.

This "Changes Being Effected" sNDA provides for changes to the carton and Drug Facts label to include the addition of the following label warnings requested in the October 31, 2014 CBE-0 supplement request letter:

> Under the Drug Facts Warnings heading "**Ask a doctor or pharmacist before use if you are taking**", adding the new bulleted statement:
>
> - methotrexate (arthritis medicine)
>
> and by revising the existing immunosuppressant drug interaction warning by adding mycophenolate mofetil:
>
> - tacrolimus or mycophenolate mofetil (immune system medicines).

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.

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 Omeprazole Delayed Release tablets, 20 mg labels submitted on December 12, 2014:

- 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

Even though no revisions were made to the 14-count immediate container (blister and bottle) labels, submit the 14-count immediate container (blister and bottle) labels as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

We remind you to implement the safety labeling changes requested in the October 31, 2014, supplement request letter as a CBE-0 supplement for the recently approved wildberry mint flavor labels.

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-029**." Approval of this submission by FDA is not required before the labeling is used.

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Mr. Jeffrey Buchanan
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5461
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Mr. Jeffrey Buchanan
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5461
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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, M.D.
Acting 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
06/11/2015