DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022032/S-021

SUPPLEMENT APPROVAL

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

Dear Ms. D'Esposito:

Please refer to your Supplemental New Drug Application (sNDA) dated February 19, 2013, received February 20, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

We acknowledge receipt of your amendments dated May 3, July 12 and 29, and August 5, 2013.

This "Prior Approval" supplemental new drug application proposes to add the following statements:

- "FDA Approved" to the 14-, 28- and 42-count blister and bottle cartons
- "14 FREE" to the 28- and 42-count blister cartons
- "28+14 FREE" to the 42-count blister carton
- "Bonus Pack! 14 Free" to the 28- and 42-count blister and bottle cartons
- "Bonus! 14 Free" to the 28- and 42-count blister and bottle cartons
- "Triple Pack Three 14-day courses of treatment" to the 42-count blister and bottle cartons

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, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labels as listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable;

Labels submitted on February 19, 2013:

- "FDA Approved" flag for the 14-, 28- and 42-count blister and bottle carton labels
- "14 FREE" flag for the 28- and 42-count blister carton labels
- "28 + 14 FREE" flag for the 42-count blister carton label

Labels submitted on May 3, 2013:

- "Bonus pack! 14 Free" flag for the 28- and 42-count blister and bottle labels
- "Triple Pack Three 14-day courses of treatment" flag for the 42-count blister and bottle labels.

Labels submitted on July 12, 2013:

- "Bonus! 14 Free" flag for the 28- and 42-count blister and bottle labels

Though no revisions were made to the 14-count immediate container (blister and bottle) labels or the 14-count inner carton label as part of this supplement, you should submit the 14-count immediate container (blister and bottle) labels and the 14-count inner carton label 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.

The final printed labeling 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 022032/S-021**." 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 questions, contact Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director (Acting)
Division of Nonprescription Clinical Evaluation
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/

THERESA M MICHELE
08/16/2013