DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022032/S-024

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 March 15, 2014, received March 18, 2014, 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 March 17 and 30, May 16, July 18, October 15, December 12, 2014, and January 30, 2015.

The October 15, 2014 submission constituted a complete response to our September 29, 2014 action letter.

This "Prior Approval" sNDA proposes to add a Wildberry Mint flavor to the already-approved, original marketed drug product.

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 and with the minor editorial revisions listed below:

- For all cartons, under the **Directions** section of the Drug Facts label, unbold the statement, "Swallow whole. Do not chew, crush or suck tablets." Please submit this change as part of your final printed labeling (FPL).

LABELING

Submit FPL, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The 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 December 12, 2014:

- Wildberry Mint 14-count immediate container (blister)
- Wildberry Mint 14-count immediate container (bottle)
- Wildberry Mint 14-count inner blister carton
- Wildberry Mint 14-, 28- and 42-count blister cartons
- Wildberry Mint 14-, 28- and 42-count bottle cartons
- Wildberry Mint 14-, 28- and 42-count blister and bottle carton PDP peel-off coupon labels
- Wildberry Mint "FDA Approved" 14-, 28- and 42-count blister and bottle carton labels
- Wildberry Mint "Bonus pack! 14 Free" 28- and 42-count blister and bottle labels
- Wildberry Mint "BONUS! 14 FREE" 28- and 42-count blister and bottle labels
- Wildberry Mint "14 FREE" 28- and 42-count blister and bottle labels
- Wildberry Mint "28 + 14 FREE" 42-count blister and bottle carton labels
- Wildberry Mint "Triple Pack Three 14-day courses of treatment" 42-count blister and bottle labels
- Wildberry Mint "3 Pack Three 14-day courses of treatment" 42-count bottle label
- Wildberry Mint "Value Pack 3-14 Tablet Bottles" 42-count bottle label

Labels submitted on January 30, 2015:

- Wildberry Mint "3 Pack Three 14-day courses of treatment" 42-count blister label
- Wildberry Mint "Value Pack 3-14 Tablet Cartons" 42-count blister label

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 022032/S-024**." 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.

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Jeffrey Buchanan, Regulatory Health Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
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/

THERESA M MICHELE
03/06/2015