DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 22032/S-037

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd
U.S. Agent-ICON Clinical Research, LLC
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Drive
Suite 300, PO Box 14353
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 5, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole 20 mg, delayed-release tablets.

This "Changes Being Effected" (CBE-0) supplement new drug application provides for the addition of a new warning to inform consumers to stop use and ask doctor if they develop a rash or joint pain in accordance with the Agency's CBE-0 Request Letter dated April 6, 2017.
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, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the tables below. The final printed labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
14-count immediate container (blister), unflavored	May 5, 2017
14-count immediate container (bottle), unflavored	May 5, 2017
14-count inner blister carton, unflavored	May 5, 2017
14-count blister carton, unflavored	May 5, 2017
14-count bottle carton, unflavored	May 5, 2017
14-count blister carton with “FDA Approved”, unflavored	May 5, 2017
14-count bottle carton with “FDA Approved”, unflavored	May 5, 2017
28-count blister carton, unflavored	May 5, 2017
28-count bottle carton, unflavored	May 5, 2017
28-count blister carton with “FDA Approved”, unflavored	May 5, 2017
28-count bottle carton with “FDA Approved”, unflavored	May 5, 2017
28-count blister carton with ”14 FREE”, unflavored	May 5, 2017
28-count bottle carton with ”14 FREE”, unflavored	May 5, 2017
28-count blister carton with “Bonus Pack! 14 Free”, unflavored	May 5, 2017
28-count bottle carton with “Bonus Pack! 14 Free”, unflavored	May 5, 2017
28-count blister carton with “Bonus! 14 Free”, unflavored	May 5, 2017
28-count bottle carton with “Bonus! 14 Free”, unflavored	May 5, 2017
42-count blister carton, unflavored	May 5, 2017
42-count bottle carton, unflavored	May 5, 2017
42-count blister carton with “FDA Approved”, unflavored	May 5, 2017

Submitted Labeling	Date Submitted
42-count bottle carton with "FDA Approved", unflavored	May 5, 2017
42-count blister carton with "14 FREE", unflavored	May 5, 2017
42-count bottle carton with "14 FREE", unflavored	May 5, 2017
42-count blister carton with "Bonus Pack! 14 Free", unflavored	May 5, 2017
42-count bottle carton with "Bonus Pack! 14 Free", unflavored	May 5, 2017
42-count blister carton with "Bonus! 14 Free", unflavored	May 5, 2017
42-count bottle carton with "Bonus! 14 Free", unflavored	May 5, 2017
42-count blister carton with "28 + 14 Free", unflavored	May 5, 2017
42-count bottle carton with "28 + 14 Free", unflavored	May 5, 2017
42-count blister carton with "3 PACK Three 14-day courses of treatment", unflavored	May 5, 2017
42-count bottle carton with "3 PACK Three 14-day courses of treatment",	May 5, 2017
42-count blister carton with "Triple Pack Three 14-day courses of treatment", unflavored	May 5, 2017
42-count bottle carton with "Triple Pack Three 14-day courses of treatment", unflavored	May 5, 2017
42-count blister carton with "Value Pack! 3-14 Tablet Cartons",	May 5, 2017
42-count bottle carton with "Value Pack! 3-14 Tablet Cartons", unflavored	May 5, 2017
Wildberry Mint flavor	
14-count immediate container (blister), wildberry mint flavor	May 5, 2017
14-count immediate container (bottle), wildberry mint flavor	May 5, 2017
14-count inner blister carton, wildberry mint flavor	May 5, 2017
14-count blister carton, wildberry mint flavor	May 5, 2017

Submitted Labeling	Date Submitted
14-count bottle carton, wildberry mint flavor	May 5, 2017
14-count blister carton with “FDA Approved”, wildberry mint flavor	May 5, 2017
14-count bottle carton with “FDA Approved”, wildberry mint flavor	May 5, 2017
28-count blister carton, wildberry mint flavor	May 5, 2017
28-count bottle carton, wildberry mint flavor	May 5, 2017
28-count blister carton with “FDA Approved”, wildberry mint flavor	May 5, 2017
28-count bottle carton with “FDA Approved”, wildberry mint flavor	May 5, 2017
28-count blister carton with “14 FREE”, wildberry mint flavor	May 5, 2017
28-count bottle carton with “14 FREE”, wildberry mint flavor	May 5, 2017
28-count blister carton with “Bonus Pack! 14 Free”, wildberry mint flavor	May 5, 2017
28-count bottle carton with “Bonus Pack! 14 Free”, wildberry mint flavor	May 5, 2017
28-count blister carton with “Bonus! 14 Free”, wildberry mint flavor	May 5, 2017
28-count bottle carton with “Bonus! 14 Free”, wildberry mint flavor	May 5, 2017
42-count blister carton, wildberry mint flavor	May 5, 2017
42-count bottle carton, wildberry mint flavor	May 5, 2017
42-count blister carton with “FDA Approved”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “FDA Approved”, wildberry mint flavor	May 5, 2017
42-count blister carton with “14 FREE”, wildberry mint flavor	May 5, 2017

Submitted Labeling	Date Submitted
42-count bottle carton with “14 FREE”, wildberry mint flavor	May 5, 2017
42-count blister carton with “Bonus Pack! 14 Free”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “Bonus Pack! 14 Free”, wildberry mint flavor	May 5, 2017
42-count blister carton with “Bonus! 14 Free”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “Bonus! 14 Free”, wildberry mint flavor	May 5, 2017
42-count blister carton with “28 + 14 Free”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “28 + 14 Free”, wildberry mint flavor	May 5, 2017
42-count blister carton with “3 PACK Three 14-day courses of treatment”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “3 PACK Three 14-day courses of treatment”, wildberry mint flavor	May 5, 2017
42-count blister carton with “Triple Pack Three 14-day courses of treatment”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “Triple Pack Three 14-day courses of treatment”, wildberry mint flavor	May 5, 2017
42-count blister carton with “Value Pack! 3-14 Tablet Cartons”, wildberry mint flavor	May 5, 2017
42-count bottle carton with “Value Pack! 3-14 Tablet Cartons”, wildberry mint flavor	May 5, 2017

The final printed labeling 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 22032/S-037**." 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. 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
10/30/2017