CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

208025Orig1s000

Trade Name:	lansoprazole delayed-release, orally disintegrating tablets, 15 mg.
Generic or Proper Name:	lansoprazole
Sponsor:	Dexcel Pharma Technologies Ltd.
Approval Date:	June 7, 2016
Indication:	Drug Facts label Use statement: treats frequent heartburn (occurs 2 or more days a week)

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208025Orig1s000

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208025

NDA APPROVAL

Dexcel Pharma Technologies Ltd.
c/o Camargo Pharmaceutical Services LLC
Attention: Ruth E. Stevens, PhD, MBA
Chief Scientific Officer, Executive Vice President
9825 Kenwood Road, Suite 203
Cincinnati, OH 45242

Dear Dr. Stevens:

Please refer to your New Drug Application (NDA) dated December 5, 2014, received December 8, 2014, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for lansoprazole delayed-release, orally disintegrating tablets, 15 mg.

This new drug application provides for the use of lansoprazole delayed-release, orally disintegrating tablets for the treatment of frequent heartburn (occurring 2 or more days a week) in adults age 18 years and older.

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 to the ***Drug Facts*** labeling listed below:

1. Under the ***Directions*** section, change the letter "C" of the first word of the last bullet, "children", from an upper case letter "C" to a lower case "c" to read:
   - children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

2. Under the "***Questions or comments?***" section, include the time the toll-free number is in operation as committed to in the May 11, 2016, submission.

We remind you that, if you should be interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14 tablets, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of limitations of use. You are encouraged to contact the Division of Nonprescription Drug Products, prior to submission of such a supplement, about the content and format of the supplement.

LABELING

Submit final printed labeling (FPL), with the revisions listed above, 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 14-count immediate container (blister) label submitted on August 6, 2015; the 14-count bottle carton and bottle carton with window, the 28-count bottle carton and bottle carton with window labels, and the Consumer Information Leaflet submitted on May 11, 2016; the 14-count immediate container (bottle) label submitted on May 16, 2016; and the 7-count immediate container (blister), the 14-count inner blister carton, the 14-, 28- and 42-count blister cartons, and the 42-count bottle carton and bottle carton with window labels submitted on May 20, 2016; and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 208025**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

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.

We are waiving the pediatric study requirement for this application because, per section 505B(a)(4)(A)(ii) of the Federal Food, Drug and Cosmetic Act, there is evidence strongly suggesting that nonprescription lansoprazole would be ineffective and unsafe in all pediatric age groups. The underlying causes for heartburn in children should be evaluated by a healthcare professional. For the pediatric population, proton pump inhibitors should be available only by prescription.

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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy 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/

KAREN M MAHONEY
06/07/2016