



NDA 208025/S-003

**SUPPLEMENT APPROVAL**

Dexcel Pharma Technologies Ltd  
c/o: Icon Clinical Research LLC (Authorized Agent)  
Attention: Amy Kneifel, RAC  
Director, Regulatory Affairs  
79 TW Alexander Drive  
4401 Research Commons Bldg, Suite 300  
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 18, 2016, 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 tablet, 15 mg.

This "Prior Approval" sNDA proposes 26 new labels with revised graphics to include a new tablet graphic, an image of a strawberry to illustrate the strawberry flavor, the modifier "24 Hour", and multiple variations of labels to include the addition of a clock graphic for three labels, the addition of the claim "Melts in your mouth Dissolves without water" on three labels, the statement "Orally Disintegrating Tablets" on three labels, the claim "Child-resistant" for three labels, and multiple bonus labels.

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. We remind you of your March 29, 2017, commitment to replace the printed 14-count inner carton labeling with the approved 14-count inner carton label once the supply is exhausted. We also remind you to remove the "New Dosage Form!" flag 6 months after introduction to the marketplace.

If you request to market other package configurations in the future (e.g., bottles containing greater than 14 capsules, package sizes greater than 42-count), we will expect submission of a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use. We encourage you to contact us about the content and format of such a supplement prior to submission.

**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 14-count inner carton and 14-, 28- and 42-

count “Child-resistant” outer carton labels submitted on April 24, 2017, and 14-, 28- and 42-count with clock graphic, “Melts in your Mouth”, and “Orally Disintegrating Tablets” outer carton, 28- and 42-count “Value Pack”, “Bonus Size! 14 Tablets Free”, “Bonus Size! 14 Free”, “Bonus! +14 FREE” and “Bonus! 14 Tablets FREE” outer carton, 28-count “Buy One 14 Count, Get One 14 Count Free” and “100% More Free! 14 Free Tablets” outer carton, and 42-count “Bonus Pack: 28 + 14 Free” outer carton labels submitted on March 29, 2017; and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

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 208025/S-003.**” 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.

## **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.

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 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

ENCLOSURE(S):  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KAREN M MAHONEY  
05/09/2017