NDA 208025/S-010

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Limited
c/o ICON Clinical Research LLC, U.S. Agent
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Dr
4401 Research Commons Bldg, Suite 300
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received July 22, 2020, 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" supplemental new drug application provides for the addition of the text "Dissolve tabs" to the outer blister cartons of lansoprazole delayed-release orally disintegrating tablet, 15 mg. In addition, the approved statement "24 Hour" is being changed to "24 HR," as well as other minor updates.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 enclosed labeling and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Date(s) Submitted
14-ct blister inner carton	August 20, 2020
14-ct outer carton (main)	August 20, 2020
14-ct outer carton ("Orally Disintegrating Tablets" stated in proximity to tablet image)	August 20, 2020
14-ct outer carton (Child-resistant)	August 20, 2020

Submitted Labeling	Date(s) Submitted
28-ct outer carton (main)	August 20, 2020
28-ct outer carton (“Orally Disintegrating Tablets” stated in proximity to tablet image)	August 20, 2020
28-ct outer carton (Value 2 Pack)	August 20, 2020
28-ct outer carton (Child-resistant)	August 20, 2020
28-ct outer carton Bonus (“Buy One 14 Count, Get One 14 Count Free!”)	August 20, 2020
28-ct outer carton Bonus (“100% More Free! 14 Free Tablets!”)	August 20, 2020
28-ct outer carton Bonus (“Bonus Size! 14 Tablets Free”)	August 20, 2020
28-ct outer carton Bonus (“Bonus Size! 14 Free”)	August 20, 2020
28-ct outer carton Bonus (“Bonus! + 14 Free”)	August 20, 2020
28-ct outer carton Bonus (“Bonus! 14 Tablets FREE”)	August 20, 2020
42-ct outer carton (main)	August 20, 2020
42-ct outer carton (“Orally Disintegrating Tablets” stated in proximity to tablet image)	August 20, 2020
42-ct outer carton (Value 3 Pack)	August 20, 2020
42-ct outer carton (Child-resistant)	August 20, 2020
42-ct outer carton Bonus (“Bonus Pack: 28 + 14 Free”)	August 20, 2020
42-ct outer carton Bonus (“Bonus Size! 14 Tablets Free”)	August 20, 2020
42-ct outer carton Bonus (“Bonus Size! 14 Free”)	August 20, 2020
42-ct outer carton Bonus (“Bonus! + 14 Free”)	August 20, 2020
42-ct outer carton Bonus (“Bonus! 14 Tablets FREE”)	August 20, 2020

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 208025/S-010**." Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future (e.g. individual containers containing greater than 14-count, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of use.

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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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 Contents of a Complete Submission for the Evaluation of Proprietary Names and PDUFA Reauthorization Performance Goals and Procedures – Fiscal Years 2018 Through 2022.)

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

the claimed indication 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 Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
11/20/2020 03:21:43 PM