NDA 214278/S-001

**SUPPLEMENT APPROVAL**

Dexcel Pharma Technologies Ltd.
Attention: Jeanne M. Novak, PhD (Authorized Agent)
Chief Executive Officer and Principal Consultant
2905 Wilderness Place, Suite 202
Boulder, CO 80301

Dear Dr. Novak:

Please refer to your supplemental new drug application (sNDA) dated and received March 11, 2021, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for esomeprazole delayed release orally disintegrating tablets, 20 mg.

This "Prior Approval" supplemental new drug application provides for:

- Addition of "Compare to the active ingredient in Nexium® 24HR*" on the principal display panel on the 2-, 14-, 28-, and 42-count outer cartons
- Addition of "This product is not manufactured or distributed by GSK, distributor of Nexium® 24HR" to the side panels of the 2-, 14-, 28-, and 42-count outer cartons
- Minor editorial revision updates (e.g., capitalization correction to the Other information heading, revises arrow positioning in the Drug Facts label, and deletion of barlines surrounding the Tips for Managing Heartburn)
- Replacement of the NDC placeholder (i.e., XXX) with 112

## 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 described below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable, and be identical to the following labeling submitted on April 22, 2021.

1. 2-count outer carton with berries image (physician sample)
2. 2-count outer carton without berries image (physician sample)
3. 14-count inner carton with berries image
4. 14-count inner carton without berries image
5. 14-count outer carton with berries image
6. 14-count outer carton without berries image
7. 28-count outer carton with berries image
8. 28-count outer carton without berries image
9. 42-count outer carton with berries image
10. 42-count outer carton without berries image

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 214278/S-001**." 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., immediate containers containing more than 14-count, package sizes more than 42-count), a prior approval labeling supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use must be submitted. We encourage you to contact us about the content and format of such a supplement prior to submission.

## 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

[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

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*.)

**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, PharmD, Regulatory Project Manager, at 301-796-0849.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURES:

- Carton Labeling

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**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.**

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/s/

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