



NDA 209400/S-012

**SUPPLEMENT APPROVAL**

Dexcel Pharma Technologies Limited  
c/o: Icon Clinical Research LLC (Authorized US Agent)  
Attention: Amy Kneifel, RAC  
Director, Regulatory Affairs  
4130 Parklake Avenue, Suite 300  
Raleigh, NC 27612

Dear Ms. Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received April 27, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed release orally disintegrating tablet, 20 mg.

This “Changes Being Effectuated” supplemental new drug application provides for an update to the storage instruction for the tablets and a warning for Severe Cutaneous Adverse Reactions (SCARs) which has been added per FDA’s Changes Being Effectuated (CBE) supplement request letter issued on March 7, 2022.

**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 in the “Drug Facts” format (21 CFR 201.66) and identical to the following:

<b>Submitted Labeling</b>	<b>Date Submitted</b>
2-Count physician sample carton	July 7, 2022
14-Count inner carton	July 7, 2022
14-Count outer carton with “FDA Approved” statement	July 7, 2022
14-Count outer carton – Main	July 7, 2022
14-Count outer carton - Child resistant	July 7, 2022

14-Count outer carton - Tablet image text	July 7, 2022
14-Count outer carton with in-pack coupon for \$X OFF 14-count DR ODT	July 7, 2022
14-Count outer carton - Sticker - HEY LOOK	July 7, 2022
14-Count outer carton - Sticker - Melts in your mouth	July 7, 2022
14-Count - IRC peel-away PDP	July 7, 2022
28-Count outer carton with "FDA Approved" statement	July 7, 2022
28-Count outer carton – Main	July 7, 2022
28-Count outer carton - Child resistant	July 7, 2022
28-Count outer carton - Tablet image text	July 7, 2022
28-Count outer carton with "Buy One 14 Count, Get One 14 Count Free!" statement	July 7, 2022
28-Count outer carton with "100% More Free! 14 Free Tablets!" statement	July 7, 2022
28-Count outer carton with "Bonus Size! 14 Tablets Free" statement	July 7, 2022
28-Count outer carton with "Bonus Size! 14 Free" statement	July 7, 2022
28-Count outer carton with "Bonus! + 14 Free" statement	July 7, 2022
28-Count outer carton with "Bonus! 14 Tablets FREE" statement	July 7, 2022
28-Count outer carton with "Value 2 pack" statement	July 7, 2022
28-Count outer carton with in-pack coupon for \$X OFF 14-count DR ODT	July 7, 2022
28-Count outer carton - Sticker - HEY LOOK	July 7, 2022
28-Count outer carton - Sticker - Melts in your mouth	July 7, 2022
28-Count - IRC peel-away PDP	July 7, 2022
42-Count outer carton with "FDA Approved" statement	July 7, 2022
42-Count outer carton – Main	July 7, 2022
42-Count outer carton - Child resistant	July 7, 2022
42-Count outer carton - Tablet image text	July 7, 2022
42-Count outer carton with "Bonus Pack: 28 + 14 Free" statement	July 7, 2022
42-Count outer carton with "Bonus Size! 14 Tablets Free" statement	July 7, 2022
42-Count outer carton with "Bonus Size! 14 Free" statement	July 7, 2022
42-Count outer carton with "Bonus! + 14 Free" statement	July 7, 2022

42-Count outer carton with “Value 3 pack” statement	July 7, 2022
42-Count outer carton with “Bonus! 14 Tablets FREE” statement	July 7, 2022
42-Count outer carton - Sticker - HEY LOOK	July 7, 2022
42-Count outer carton - Sticker - Melts in your mouth	July 7, 2022
42-Count - IRC peel-away PDP	July 7, 2022

We also recommend a minor formatting change in the FPL to include a period after the first statement in the updated SCARs warning (i.e., “do not use if you are allergic to omeprazole.”).

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 209400/S-012.**” 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 FDA.gov.<sup>2</sup> 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.

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

If you have any questions, call Cynthia Kim, PharmD, Senior Regulatory Project Manager at 301-796-0879.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE:

- 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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