NDA 209400/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 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 June 10, 2020, 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 "Prior Approval" supplemental new drug application provides for the addition of the statement "Dissolve tabs" to the inner and outer blister cartons of omeprazole delayed-release orally disintegrating tablet, 20 mg.

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), where applicable and be identical to the following:

Submitted Labeling	Date(s) Submitted
14-ct Inner Carton	June 10, 2020 Revised: August 13, 2020
14-ct Physician Sample Carton	June 10, 2020 Revised: August 13, 2020
14-ct Blister Carton with "FDA Approved" statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with "FDA Approved" statement	June 10, 2020 Revised: August 13, 2020

Submitted Labeling	Date(s) Submitted
42-ct Outer Carton with “FDA Approved” statement	June 10, 2020 Revised: August 13, 2020
14-ct Outer Carton – Main	June 10, 2020 Revised: August 13, 2020
14-ct Outer Carton – Child resistant	June 10, 2020 Revised: August 13, 2020
14-ct Outer Carton – tablet image text (to be used with promotional stickers)	June 10, 2020 Revised: August 13, 2020
Instant Redeemable coupon (IRC) to be placed on 14-ct Outer Carton	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton – Main	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton – Child resistant	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with “Buy One 14 Count, Get One 14 Count Free!” statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with “100% More Free! 14 Free Tablets” statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with “Bonus Size! 14 Tablets Free” statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with “Bonus Size! 14 Free” statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with “Bonus! +14 Free” statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton with “Bonus! 14 Tablets FREE” statement	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton –tablet image text	June 10, 2020 Revised: August 13, 2020
28-ct Outer Carton –Value 2 Pack	June 10, 2020 Revised: August 13, 2020
Instant Redeemable coupon (IRC) to be placed on 28-ct Outer Carton	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton – Main	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton – Child resistant	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton with “Bonus Pack 28+14 Free” statement	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton with “Bonus Size! 14 Tablets Free” statement	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton with “Bonus Size! 14 Free” statement	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton with “Bonus! + 14 Free” statement	June 10, 2020 Revised: August 13, 2020

Submitted Labeling	Date(s) Submitted
42-ct Outer Carton –tablet image text	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton – Value 3 Pack	June 10, 2020 Revised: August 13, 2020
42-ct Outer Carton with “Bonus! 14 Tablets Free” statement	June 10, 2020 Revised: August 13, 2020
Instant Redeemable coupon (IRC) to be placed on 42-ct Outer Carton	June 10, 2020 Revised: August 13, 2020
“Melts in your mouth” Promotional Sticker to be placed on 14-ct Outer Carton	June 10, 2020 Revised: August 13, 2020
“Hey Look” Promotional Sticker to be placed on 14-ct Blister Carton	June 10, 2020 Revised: August 13, 2020
“Melts in your mouth” Promotional Sticker to be placed on 28-ct Blister Carton	June 10, 2020 Revised: August 13, 2020
“Hey Look” Promotional Sticker to be placed on 28-ct Blister Carton	June 10, 2020 Revised: August 13, 2020
“Melts in your mouth” Promotional Sticker to be placed on 42-ct Blister Carton	June 10, 2020 Revised: August 13, 2020
“Hey Look” Promotional Sticker to be placed on 42-ct Blister Carton	June 10, 2020 Revised: August 13, 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 209400/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 immediate containers containing greater than 14-count, total package sizes greater than 42-count), a prior approval 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.

[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.

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.

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 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

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

ENCLOSURE:

- Carton Labeling

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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
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