NDA 022032/S-057

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Limited
c/o ICON Clinical Research LLC (Authorized Agent)
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
4130 Parklake Avenue
Suite 400
Raleigh, NC 27612

Dear Ms. Kneifel:

Please refer to your supplemental new drug application (sNDA) dated and received April 5, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablets, 20 mg.

This "Changes Being Effected" supplemental new drug application provides for editorial changes to the principal display panel of the outer blister and bottle cartons, and the bottle labels for the unflavored and Wild Berry Mint flavored products, which are in line with the approved Cool Mint artwork from Supplement 052, approved on October 1, 2021. Additionally, a warning for Severe Cutaneous Adverse Reactions (SCARs) has been added to the labeling per the Agency's Changes Being Effected (CBE) supplement request letter issued on March 7, 2022, for omeprazole delayed-release tablets.

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 identical to the following:

Submitted Labeling	Date Submitted
Unflavored Tablets	
14-Count outer carton (blister)	May 13, 2022

Submitted Labeling	Date Submitted
14-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
14-Count outer carton (blister) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
14-Count outer carton (blister) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
14-Count inner carton (blister)	May 13, 2022
14-Count outer carton (bottle)	May 13, 2022
14-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022
14-Count outer carton (bottle) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
14-Count outer carton (bottle) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
14-Count immediate container (bottle)	May 13, 2022
28-Count outer carton (blister)	May 13, 2022
28-Count outer carton with “14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “Bonus! 14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “Bonus Pack! 14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
28-Count outer carton (blister) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
28-Count outer carton (blister) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
28-Count outer carton (bottle)	May 13, 2022
28-Count outer carton with “14 Free” statement (bottle)	May 13, 2022
28-Count outer carton with “Bonus! 14 Free” statement (bottle)	May 13, 2022
28-Count outer carton with “Bonus Pack! 14 Free” statement (bottle)	May 13, 2022
28-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022
28-Count outer carton (bottle) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
28-Count outer carton (bottle) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
42-Count outer carton (blister)	May 13, 2022
42-Count outer carton with “3 PACK Three 14-day courses of treatment” statement (blister)	May 13, 2022
42-Count outer carton with “14 Free” statement (blister)	May 13, 2022
42-Count outer carton with “28 + 14 FREE” statement (blister)	May 13, 2022
42-Count outer carton with “Bonus! 14 Free” statement (blister)	May 13, 2022
42-Count outer carton with “Bonus Pack! 14 Free” statement (blister)	May 13, 2022
42-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022

Submitted Labeling	Date Submitted
42-Count outer carton with “Triple Pack Three 14-day courses of treatment” statement (blister)	May 13, 2022
42-Count outer carton with “Value Pack Three - 14 tablet cartons” statement (blister)	May 13, 2022
42-Count outer carton (bottle)	May 13, 2022
42-Count outer carton with “3 PACK Three 14-day courses of treatment” statement (bottle)	May 13, 2022
42-Count outer carton with “14 Free” statement (bottle)	May 13, 2022
42-Count outer carton with “28 + 14 FREE” statement (bottle)	May 13, 2022
42-Count outer carton with “Bonus! 14 Free” statement (bottle)	May 13, 2022
42-Count outer carton with “Bonus Pack! 14 Free” statement (bottle)	May 13, 2022
42-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022
42-Count outer carton with “Triple Pack Three 14-day courses of treatment” statement (bottle)	May 13, 2022
42-Count outer carton with “Value Pack Three - 14 tablet bottles” statement (bottle)	May 13, 2022
14-Count Peel-Away PDP IRC (blister)	May 13, 2022
14-Count IRC (bottle)	May 13, 2022
28-Count Peel-Away PDP IRC (blister)	May 13, 2022
28-Count IRC (bottle)	May 13, 2022
42-Count Peel-Away PDP IRC (blister)	May 13, 2022
42-Count IRC (bottle)	May 13, 2022
Cool Mint Flavored Tablets	
2-Count physician sample outer carton (blister)	May 13, 2022
14-Count outer carton (blister)	May 13, 2022
14-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
14-Count inner carton (blister)	May 13, 2022
14-Count outer carton (bottle)	May 13, 2022
14-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022
28-Count outer carton (blister)	May 13, 2022
28-Count outer carton with “14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “Bonus! 14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “Bonus Pack! 14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
28-Count outer carton (bottle)	May 13, 2022
28-Count outer carton with “14 Free” statement (bottle)	May 13, 2022
28-Count outer carton with “Bonus! 14 Free” statement (bottle)	May 13, 2022
28-Count outer carton with “Bonus Pack! 14 Free” statement (bottle)	May 13, 2022
28-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022

Submitted Labeling	Date Submitted
42-Count outer carton (blister)	May 13, 2022
42-Count outer carton with “3 PACK Three 14-day courses of treatment” statement (blister)	May 13, 2022
42-Count outer carton with “14 Free” statement (blister)	May 13, 2022
42-Count outer carton with “28 + 14 FREE” statement (blister)	May 13, 2022
42-Count outer carton with “Bonus! 14 Free” statement (blister)	May 13, 2022
42-Count outer carton with “Bonus Pack! 14 Free” statement (blister)	May 13, 2022
42-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
42-Count outer carton with “Triple Pack Three 14-day courses of treatment” statement (blister)	May 13, 2022
42-Count outer carton with “Value Pack Three - 14 tablet cartons” statement (blister)	May 13, 2022
42-Count outer carton (bottle)	May 13, 2022
42-Count outer carton with “3 PACK Three 14-day courses of treatment” statement (bottle)	May 13, 2022
42-Count outer carton with “14 Free” statement (bottle)	May 13, 2022
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42-Count outer carton with “Bonus! 14 Free” statement (bottle)	May 13, 2022
42-Count outer carton with “Bonus Pack! 14 Free” statement (bottle)	May 13, 2022
42-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022
42-Count outer carton with “Triple Pack Three 14-day courses of treatment” statement (bottle)	May 13, 2022
42-Count outer carton with “Value Pack Three – 14 tablet bottles” statement (bottle)	May 13, 2022
Wild Berry Mint Flavored Tablets	
14-Count outer carton (blister)	May 13, 2022
14-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
14-Count outer carton (blister) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
14-Count outer carton (blister) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
14-Count inner carton (blister)	May 13, 2022
14-Count outer carton (bottle)	May 13, 2022
14-Count outer carton with “FDA Approved” statement (bottle)	May 13, 2022
14-Count outer carton (bottle) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
14-Count outer carton (bottle) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
14-Count immediate container (bottle)	May 13, 2022
28-Count outer carton (blister)	May 13, 2022

Submitted Labeling	Date Submitted
28-Count outer carton with “14 Free” statement (blister)	May 13, 2022
28-Count outer carton with “Bonus! 14 Free” statement (blister)	May 13, 2022
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28-Count outer carton with “FDA Approved” statement (blister)	May 13, 2022
28-Count outer carton (blister) with in-pack coupon for FREE 14-count DR ODT	May 13, 2022
28-Count outer carton (blister) with in-pack coupon for $X OFF 14-count DR ODT	May 13, 2022
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Submitted Labeling	Date Submitted
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14-Count IRC (bottle)	May 13, 2022
28-Count Peel-Away PDP IRC (blister)	May 13, 2022
28-Count IRC (bottle)	May 13, 2022
42-Count Peel-Away PDP IRC (blister)	May 13, 2022
42-Count IRC (bottle)	May 13, 2022

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 022032/S-057**." Approval of this submission by FDA is not required before the labeling is used.

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."

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

[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

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, PharmD, 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(S)

- Carton and Container 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
09/30/2022 03:45:39 PM