NDA 209400/S-007

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 on October 23, 2019, 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, 20mg.

This "Prior Approval" supplemental new drug application provides for the addition of promotional sticker labeling to the outer cartons of omeprazole delayed-release orally disintegrating 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 be identical to the following labels submitted on December 18, 2019:

1. 14-count sticker labeling with "Melts in your mouth" flag
2. 14-count sticker labeling with "Hey Look" and "Melts in your mouth" flags
3. 28-count sticker labeling with "Melts in your mouth" flag
4. 28-count sticker labeling with "Hey Look" and "Melts in your mouth" flags
5. 42-count sticker labeling with "Melts in your mouth" flag
6. 42-count sticker labeling with "Hey Look" and "Melts in your mouth" flags

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-007**." 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.

REPORTING REQUIREMENTS

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

[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

If you have any questions, call Helen Lee, Regulatory Project Manager, at 301-796-6848.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Acting Deputy Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs I
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

KAREN M MAHONEY
04/29/2020 01:35:22 PM