NDA 022032/S-052

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Limited
c/o: Icon Clinical Research LLC (Authorized 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 2, 2021, 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 "Prior Approval" supplemental new drug application provides for the addition of a cool mint flavored formulation and associated labeling.

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.

Cool Mint Flavored Tablets Label Submitted on August 12, 2021:
1. 2-count immediate container label

Cool Mint Flavored Tablets Labeling Submitted on July 26, 2021:
2. 14-count immediate container (blister)
3. 14-count immediate container (bottle)
4. 14-count inner carton
5. 2-count physician sample outer carton (blister)
6. 14-count outer carton (blister)
7. 14-count outer carton with the "FDA Approved" statement (blister)

8. 14-count outer carton (bottle)
9. 14-count outer carton with the “FDA Approved” statement (bottle)
10. 28-count outer carton (blister)
11. 28-count outer carton with the “14 Free” statement (blister)
12. 28-count outer carton with the “Bonus! 14 Free” statement (blister)
13. 28-count outer carton with the “Bonus Pack! 14 Free” statement (blister)
14. 28-count outer carton with the “FDA Approved” statement (blister)
15. 28-count outer carton (bottle)
16. 28-count outer carton with the “14 Free” statement (bottle)
17. 28-count outer carton with the “Bonus! 14 Free” statement (bottle)
18. 28-count outer carton with the “Bonus Pack! 14 Free” statement (bottle)
19. 28-count outer carton with the “FDA Approved” statement (bottle)
20. 42-count outer carton (blister)
21. 42-count outer carton with the “14 Free” statement (blister)
22. 42-count outer carton with the “Bonus! 14 Free” statement (blister)
23. 42-count outer carton with the “Bonus Pack! 14 Free” statement (blister)
24. 42-count outer carton with the “FDA Approved” statement (blister)
25. 42-count outer carton with the “3 PACK Three 14-day courses of treatment” statement (blister)
26. 42-count outer carton with the “28 + 14 FREE” statement (blister)
27. 42-count outer carton with the “Value Pack! Three- 14 Tablet Cartons” statement (blister)
28. 42-count outer carton with the “Triple Pack Three 14-day courses of treatment” statement (blister)
29. 42-count outer carton (bottle)
30. 42-count outer carton with the “14 Free” statement (bottle)
31. 42-count outer carton with the “Bonus! 14 Free” statement (bottle)
32. 42-count outer carton with the “Bonus Pack! 14 Free” statement (bottle)
33. 42-count outer carton with the “FDA Approved” statement (bottle)
34. 42-count outer carton with the “3 PACK Three 14-day courses of treatment” statement (bottle)
35. 42-count outer carton with the “28 + 14 FREE” statement (bottle)
36. 42-count outer carton with the “Value Pack! Three- 14 Tablet Bottles” statement (bottle)
37. 42-count outer carton with the “Triple Pack Three 14-day courses of treatment” statement (bottle)
38. 14-count IRC (blister)
39. 14-count IRC (bottle)
40. 28-count IRC (blister)
41. 28-count IRC (bottle)
42. 42-count IRC (blister)
43. 42-count IRC (bottle)

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-052**." 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 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).

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[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 Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director (Acting)
Division of Nonprescription Drugs I
Office of Nonprescription 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
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