DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022032/S-038

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd
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 May 19, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for omeprazole delayed-release tablet, 20 mg.

This "Prior Approval" sNDA application provides for eighty-two labels with the following changes:

- Addition of the statement "Compare to Prilosec OTC®*" with the following disclaimer: "*This product is not manufactured or distributed by Proctor & Gamble, distributor of Prilosec OTC®" on the principal display panel (PDP) and instantly redeemable coupons (IRCs)
- Revisions to the PDP (e.g., moving the "Treats Frequent Heartburn" flag and the NDC number)
- Revision to the 'Warnings' heading of the Drug Facts label under the '**Do not use if you have**' and '**Ask a doctor before use**' subheadings to align with the approved labeling of the listed drug, Prilosec OTC®
- Minor editorial revisions to the manufacturer information (e.g., deletion of a period on Dexcel Pharma Technologies Ltd line, deletion of comma after Yokneam)
- Deletion of "LOT NO" and "EXP" printed text and the statement "Treat My Heartburn.com" and associated graphic from all carton labels and IRCs

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 agreed-upon labeling text. If you intend to market other package configurations in the future (e.g., bottles containing greater than 14 capsules, package sizes greater than 42-count), we will expect submission of a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use. We encourage you to contact us about the content and format of such a supplement prior to submission.

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 labels submitted on August 16, 2017 and listed below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Unflavored product labels:

1. 14-count immediate container (blister)
2. 14-count immediate container (bottle)
3. 14-count inner carton (blister)
4. 14-count outer carton (blister) with the 'Compare to Prilosec OTC®*' flag
5. 14-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' flag
6. 14-count outer carton (blister) with the 'Compare to Prilosec OTC®*' and 'FDA Approved' flags
7. 14-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' and 'FDA Approved' flags
8. 28-count outer carton (blister) with the 'Compare to Prilosec OTC®*' flag
9. 28-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' flag
10. 28-count outer carton (blister) with the 'Compare to Prilosec OTC®*' and 'FDA Approved' flags
11. 28-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' and 'FDA Approved' flags
12. 28-count outer carton (blister) with the 'Compare to Prilosec OTC®*' and '14 FREE' flags
13. 28-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' and '14 FREE' flags
14. 28-count outer carton (blister) with the 'Compare to Prilosec OTC®*' and 'Bonus! 14 Free' flags
15. 28-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' and 'Bonus! 14 Free' flags
16. 28-count outer carton (blister) with the 'Compare to Prilosec OTC®*' and 'Bonus Pack! 14 Free' flags
17. 28-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' and 'Bonus Pack! 14 Free' flags
18. 42-count outer carton (blister) with the 'Compare to Prilosec OTC®*' flag
19. 42-count outer carton (bottle) with the 'Compare to Prilosec OTC®*' flag

20. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
21. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
22. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘14 FREE’ flags
23. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘14 FREE’ flags
24. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘28 + 14 FREE’ flags
25. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘28 + 14 FREE’ flags
26. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus! 14 Free’ flags
27. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus! 14 Free’ flags
28. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus Pack! 14 Free’ flags
29. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus Pack! 14 Free’ flags
30. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Triple Pack’ flags
31. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Triple Pack’ flags
32. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘3 Pack’ flags
33. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘3 Pack’ flags
34. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Value Pack’ flags
35. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Value Pack’ flags

<u>Wildberry mint flavored product labels:</u>

36. 14-count immediate container (blister)
37. 14-count immediate container (bottle)
38. 14-count inner carton (blister)
39. 14-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ flag
40. 14-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ flag
41. 14-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
42. 14-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
43. 28-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ flag
44. 28-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ flag
45. 28-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags

46. 28-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
47. 28-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ’14 FREE’ flags
48. 28-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ’14 FREE’ flags
49. 28-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus! 14 Free’ flags
50. 28-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus! 14 Free’ flags
51. 28-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ’Bonus Pack! 14 Free’ flags
52. 28-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ’Bonus Pack! 14 Free’ flags
53. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ flag
54. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ flag
55. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
56. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘FDA Approved’ flags
57. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘14 FREE’ flags
58. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘14 FREE’ flags
59. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘28 + 14 FREE’ flags
60. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘28 + 14 FREE’ flags
61. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus! 14 Free’ flags
62. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus! 14 Free’ flags
63. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus Pack! 14 Free’ flags
64. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Bonus Pack! 14 Free’ flags
65. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Triple Pack’ flags
66. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Triple Pack’ flags
67. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘3 Pack’ flags
68. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘3 Pack’ flags
69. 42-count outer carton (blister) with the ‘Compare to Prilosec OTC®*’ and ‘Value Pack’ flags
70. 42-count outer carton (bottle) with the ‘Compare to Prilosec OTC®*’ and ‘Value Pack’ flags

Instantly Redeemable Coupon (IRC)

71. 14-count IRC for unflavored carton (blister)
72. 14-count IRC for unflavored carton (bottle)
73. 28-count IRC for unflavored carton (blister)
74. 28-count IRC for unflavored carton (bottle)
75. 42-count IRC for unflavored carton (blister)
76. 42-count IRC for unflavored carton (bottle)
77. 14-count IRC for wildberry mint carton (blister)
78. 14-count IRC for wildberry mint carton (bottle)
79. 28-count IRC for wildberry mint carton (blister)
80. 28-count IRC for wildberry mint carton (bottle)
81. 42-count IRC for wildberry mint carton (blister)
82. 42-count IRC for wildberry mint carton (bottle)

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 022032/S-038**." 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. 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 titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
11/13/2017