



NDA 022032/S-041

**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 October 8, 2018, and received October 9, 2018, 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 submitted in response to FDA’s June 29, 2018, supplement request letter provides for the following changes:

- Replaces the list of interacting drugs under the Drug Facts Labeling Warnings subheading “Ask a doctor or pharmacist before use if you are” with the warning “taking a prescription drug. Acid reducers may interact with certain prescription drugs.”
- Revisions to the principal display panel (PDP) (e.g., font color changes and layout re-design; addition of “May take 1 to 4 days for full effect”, “Actual size” (14-count inner carton), “24 HR” and clock image; removal of “Occurring **2 Or More Days a Week**” from the “Treats **Frequent** Heartburn!” flag, removal of the color background from the bonus and “Compare to Prilosec OTC®\*” statements; and revision to the wildberry mint coated tablet statement.
- Revision to the placement of the “X BOTTLES INSIDE” statement on the outer carton labeling for all bottled products.

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.

In addition, you have agreed to replace the COSTCO (Kirkland Signature distributor) display trays labeled with the unapproved labeling statement “<sup>(b) (4)</sup>” with new display trays labeled with the approved statement “Compare to Prilosec OTC<sup>(®)</sup>”.

## **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 October 8, 2018, listed below, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

### Unflavored product labels:

1. 14-count immediate container (bottle)
2. 14-count inner carton (blister)
3. 14-count outer carton (blister)
4. 14-count outer carton (bottle)
5. 14-count “FDA Approved” outer carton (blister)
6. 14-count “FDA Approved” outer carton (bottle)
7. 28-count outer carton (blister)
8. 28-count outer carton (bottle)
9. 28-count “FDA Approved” outer carton (blister)
10. 28-count “FDA Approved” outer carton (bottle)
11. 28-count “14 FREE” outer carton (blister)
12. 28-count “14 FREE” outer carton (bottle)
13. 28-count “Bonus! 14 Free” outer carton (blister)
14. 28-count “Bonus! 14 Free” outer carton (bottle)
15. 28-count “Bonus Pack! 14 Free” outer carton (blister)
16. 28-count “Bonus Pack! 14 Free” outer carton (bottle)
17. 42-count outer carton (blister)
18. 42-count outer carton (bottle)
19. 42-count “FDA Approved” outer carton (blister)
20. 42-count “FDA Approved” outer carton (bottle)
21. 42-count “14 FREE” outer carton (blister)
22. 42-count “14 FREE” outer carton (bottle)
23. 42-count “28 + 14 FREE” outer carton (blister)
24. 42-count “28 + 14 FREE” outer carton (bottle)
25. 42-count “Bonus! 14 Free” outer carton (blister)
26. 42-count “Bonus! 14 Free” outer carton (bottle)
27. 42-count “Bonus Pack! 14 Free” outer carton (blister)
28. 42-count “Bonus Pack! 14 Free” outer carton (bottle)
29. 42-count “Triple Pack” outer carton (blister)
30. 42-count “Triple Pack” outer carton (bottle)
31. 42-count “3 Pack” outer carton (blister)
32. 42-count “3 Pack” outer carton (bottle)
33. 42-count “Value Pack” outer carton (blister)
34. 42-count “Value Pack” outer carton (bottle)

Wildberry mint product labels:

35. 14-count immediate container (bottle)
36. 14-count inner carton (blister)
37. 14-count outer carton (blister)
38. 14-count outer carton (bottle)
39. 14-count "FDA Approved" outer carton (blister)
40. 14-count "FDA Approved" outer carton (bottle)
41. 28-count outer carton (blister)
42. 28-count outer carton (bottle)
43. 28-count "FDA Approved" outer carton (blister)
44. 28-count "FDA Approved" outer carton (bottle)
45. 28-count "14 FREE" outer carton (blister)
46. 28-count "14 FREE" outer carton (bottle)
47. 28-count "Bonus! 14 Free" outer carton (blister)
48. 28-count "Bonus! 14 Free" outer carton (bottle)
49. 28-count "Bonus Pack! 14 Free" outer carton (blister)
50. 28-count "Bonus Pack! 14 Free" outer carton (bottle)
51. 42-count outer carton (blister)
52. 42-count outer carton (bottle)
53. 42-count "FDA Approved" outer carton (blister)
54. 42-count "FDA Approved" outer carton (bottle)
55. 42-count "14 FREE" outer carton (blister)
56. 42-count "14 FREE" outer carton (bottle)
57. 42-count "28 + 14 FREE" outer carton (blister)
58. 42-count "28 + 14 FREE" outer carton (bottle)
59. 42-count "Bonus! 14 Free" outer carton (blister)
60. 42-count "Bonus! 14 Free" outer carton (bottle)
61. 42-count "Bonus Pack! 14 Free" outer carton (blister)
62. 42-count "Bonus Pack! 14 Free" outer carton (bottle)
63. 42-count "Triple Pack" outer carton (blister)
64. 42-count "Triple Pack" outer carton (bottle)
65. 42-count "3 Pack" outer carton (blister)
66. 42-count "3 Pack" outer carton (bottle)
67. 42-count "Value Pack" outer carton (blister)
68. 42-count "Value Pack" outer carton (bottle)

Instantly Redeemable Coupon (IRC)

69. 14-count IRC for unflavored carton (blister)
70. 14-count IRC for unflavored carton (bottle)
71. 28-count IRC for unflavored carton (blister)
72. 28-count IRC for unflavored carton (bottle)
73. 42-count IRC for unflavored carton (blister)
74. 42-count IRC for unflavored carton (bottle)
75. 14-count IRC for wildberry mint carton (blister)
76. 14-count IRC for wildberry mint carton (bottle)

- 77. 28-count IRC for wildberry mint carton (blister)
- 78. 28-count IRC for wildberry mint carton (bottle)
- 79. 42-count IRC for wildberry mint carton (blister)
- 80. 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-041.**” 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.

### **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

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**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.**  
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/s/  
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