

NDA 21229/S-035

## SUPPLEMENT APPROVAL

Proctor and Gamble Company  
(Authorized Agent for AstraZeneca Pharmaceuticals, LP)  
Attention: Maria Petrey, MS, RAC  
Regulatory Affairs Manager  
8700 Mason-Montgomery Road  
Mason, OH 45040-9462

Dear Ms. Petrey:

Please refer to your supplemental new drug application (sNDA) dated and received April 13, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC (omeprazole magnesium) delayed-release tablet, 20 mg.

This “Changes Being Effected” supplemental new drug application provides for an update under the “Allergy alert” warning on the Drug Facts label in response to the Agency’s CBE Supplement Request letter dated March 7, 2022.

### **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 labeling submitted on June 17, 2022:

#### **Original**

1. 14-count outer carton (base carton) with “See current Drug Facts” flag
2. 14-count inner carton with “See current Drug Facts” flag
3. 28-count outer carton (base carton) with “See current Drug Facts” flag
4. 42-count outer carton (base carton) with “See current Drug Facts” flag
5. 2-count tip card sample carton (sachet) with “See current Drug Facts” flag
6. 42-count Bonus Pack (i.e., 3-pack of 14-count side-by-side with white background for lot code) outer carton (base carton) with “See current Drug Facts” flag

7. 42-count Bonus Pack (i.e., 3-pack of 14-count side-by-side with purple background for lot code) outer carton (base carton) with “See current Drug Facts” flag
8. 42-count Club Pack (i.e., Fat Man Bonus) outer carton (base carton) with “See current Drug Facts” and “14 Bonus Tablets” flags

#### Wildberry Flavor

9. 14-count outer carton (base carton) with “See current Drug Facts” flag
10. 14-count inner carton with “See current Drug Facts” flag
11. 42-count outer carton (base carton) with “See current Drug Facts” flag

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 21229/S-035.**” 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., individual immediate containers containing greater than 14-count, total package sizes greater than 42-count), a prior approval 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.<sup>2</sup> 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).

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<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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

Sincerely,

*{See appended electronic signature page}*

Jody Green, MD  
Deputy Director for Safety  
Division of Nonprescription Drugs I  
Office of Nonprescription Drugs  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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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JODY E GREEN  
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