



NDA 204655/S-018

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC d/b/a Haleon
(Authorized Agent for AstraZeneca Pharmaceuticals LP)
Attention: Misha Mehta
Senior Associate, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Ms. Mehta:

Please refer to your supplemental new drug application (sNDA) dated and received April 6, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium 24HR (esomeprazole magnesium) delayed-release capsule, 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 labels submitted on the following dates:

May 27, 2022:

1. 2-count immediate container (Nexium 24HR capsules)
2. 2-count immediate container (Clear Minis)
3. 2-count sample outer carton (Nexium 24HR capsules)
4. 2-count sample outer carton (Clear Minis)

April 6, 2022:

5. 14-count immediate container (Nexium 24HR capsules)
6. 14-count immediate container (Clear Minis)
7. 14-count immediate container (Nexium 24HR capsules/non-child-resistant)

8. 14-count outer carton (Nexium 24HR capsules)
9. 14-count outer carton (Clear Minis)
10. 28-count outer carton (Nexium 24HR capsules/non-child resistant)
11. 42-count outer carton (Nexium 24HR capsules)
12. 42-count outer carton (backer card/Nexium 24HR capsules)
13. 42-count outer carton (Clear Minis)

We remind of your commitment dated August 1, 2022, to apply boldface type to the statement of identity on all outer carton labeling in the next annual report.

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 204655/S-018.**” 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.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, PharmD, Safety Regulatory Project Manager, at 301-796-6848.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
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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