

NDA 204655/S-014

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: Lydia Wen
Senior Associate, US Regulatory Affairs
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Ms. Wen:

Please refer to your supplemental new drug application (sNDA) dated and received on March 15, 2019, 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 "Prior Approval" supplemental new drug application provides for the copackaging of a giveaway (pillbox or tote bag) with the 42-count Nexium 24HR (esomeprazole magnesium) drug product. In addition, the outer carton labeling (backer card) includes text that promotes the giveaway on the principal display panel.

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 September 8, 2020:

1. 42-count outer carton (backer card copackaged with tote bag)
2. Tote bag pouch
3. Tote bag
4. 42-count outer carton (backer card copackaged with pillbox)
5. Pillbox

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-014.**” 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 Cynthia Kim, Regulatory Project Manager,
at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Acting Deputy Director, Office of Nonprescription
Drugs
Acting Director, Division of Nonprescription Drugs I
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/

KAREN M MAHONEY
12/04/2020 11:09:37 AM