



NDA 204655/S-011

**SUPPLEMENT APPROVAL**

Pfizer Inc. (Authorized Agent for AstraZeneca, Inc.)  
Attention: Erica Sinclair  
Director, Regulatory Affairs  
Worldwide Regulatory Strategy and New Ventures  
1 Giralda Farms  
Madison, NJ 07490

Dear Ms. Sinclair:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 5, 2018, 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 “**Ask a doctor or pharmacist before use if you are** taking a prescription drug. Acid reducers may interact with certain prescription drugs.” This update to the drug-drug interaction warning is in response to the Agency’s communications of June 29 and August 10, 2018.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

**LABELING**

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the labeling listed in the below table and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission Date
2-count sample carton (blister)	October 5, 2018
14-count immediate container (bottle), child resistant	October 5, 2018
14-count immediate container (bottle), non-child resistant	October 5, 2018
14-count carton (bottle)	October 5, 2018

14-count Club carton with backer card (bottle)	October 5, 2018
28-count carton (bottle), non-child resistant	October 5, 2018
42-count carton (bottle)	October 5, 2018
42-count Club carton with backer card (bottle)	October 5, 2018
2-count sample carton (blister), <i>ClearMinis</i> <sup>TM</sup>	October 5, 2018
14-count immediate container (bottle), <i>ClearMinis</i> <sup>TM</sup>	October 5, 2018
14-count carton (bottle), <i>ClearMinis</i> <sup>TM</sup>	October 5, 2018
42-count carton (bottle), <i>ClearMinis</i> <sup>TM</sup>	October 5, 2018
42-count Club carton with backer card, (bottle) <i>ClearMinis</i> <sup>TM</sup>	October 5, 2018

The final printed labeling 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 (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 204655/S-011**” Approval of this submission by FDA is not required before the labeling is used. We remind you to remove warning flag on the Principal Display Panel six months after label is marketed.

If you are interested in marketing other package configurations in the future, (e.g., bottles containing greater than 14 tablets, package sizes greater than 42-count), a prior approval labeling supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use must be submitted.

In addition, prior approval labeling supplements must be submitted for the following labels that are currently not marketed if you plan to market them in the future:

- 28-count carton with Child Resistant closure
- 28-count Club pack

## **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 CAPT Janice Adams-King, Safety Regulatory Health Project Manager, at 301-796-3713.

Sincerely,

*{See appended electronic signature page}*

Valerie Pratt, MD  
Deputy Director for Safety  
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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VALERIE S PRATT  
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