DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 204655/S-009

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Nicola Romano
Director, Regulatory Affairs
1 Giralda Farms
Madison, NJ 07940

Dear Mr. Romano:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 24, 2017, 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" (CBE-0) sNDA, submitted in response to the Agency's April 6, 2017, CBE-0 Supplement Request Letter, adds a new warning to the Drug Facts labeling to instruct consumers to stop use and ask a doctor if "you develop a rash or joint pain."

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 submitted labeling identified in the table below. The final printed labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission Date
2-count sample carton (blister)	July 24, 2017
14-count immediate container (bottle), child resistant	July 24, 2017
14-count immediate container (bottle), non-child resistant	July 24, 2017
14-count carton (bottle)	July 24, 2017
14-count Club carton with backer card (bottle)	July 24, 2017
28-count carton (bottle), non-child resistant	July 24, 2017

42-count carton (bottle)	July 24, 2017
42-count Club carton with backer card (bottle)	July 24, 2017
2-count sample carton (blister), *ClearMinis*™	July 24, 2017
14-count immediate container (bottle), *ClearMinis*™	July 24, 2017
14-count carton (bottle), *ClearMinis*™	July 24, 2017
42-count carton (bottle), *ClearMinis*™	July 24, 2017
42-count Club carton with backer card, (bottle) *ClearMinis*™	July 24, 2017

In addition, submit prior approval labeling supplements for the following products if you plan to market them in the future:

- 28-count carton with child-resistant closure
- 28-count Club pack

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – 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 204655/S-009.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that, if you should be interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14 tablets, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of limitations of use. You are encouraged to contact the Division of Nonprescription Drug Products, prior to submission of such a supplement, about the content and format of the supplement.

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 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
01/24/2018