DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204655/S-001

SUPPLEMENT APPROVAL

Pfizer Consumer Healthcare
Attention: Amrita Raman
Manager, U.S. Regulatory Affairs
1 Giralda Farms
Madison, NJ 07940

Dear Ms. Raman:

Please refer to your Supplemental New Drug Application (sNDA) dated April 4, 2014, received April 4, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium® 24HR (esomeprazole magnesium) delayed-release capsules, 22.3 mg.

We acknowledge receipt of your amendments dated May 30, June 3, August 27, and September 30, 2014.

This "Prior Approval" sNDA proposes the following changes: child-resistant, peel-and-push through style aluminum laminate blister as an alternate container closure system for the drug product as well as changes to the following labels:

- 2-count blister card (immediate container label)
- 2-count "sample" carton 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 agreed-upon labeling text. We remind you to remove the "New" flag after six months of marketing and to submit final printed labeling (FPL) without the "FPO" stamped text on the Drug Facts label.

LABELING

Submit FPL as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to: the 2-count immediate container (blister pack) submitted on June 3, 2014, and the 2-count carton labeling submitted on September 30, 2014. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL 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 (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on

heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 204655/S-001**." Approval of this submission by FDA is not required before the labeling is used.

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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 questions, contact Jeffrey Buchanan, Regulatory Health Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Karen Mahoney, M.D.
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

KAREN M MAHONEY
10/03/2014