CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

207920Orig1s000

Trade Name:	Nexium 24HR delayed-release tablets, 20 mg.
Generic Name:	esomeprazole
Sponsor:	Pfizer, Inc.
Approval Date:	November 23, 2015
Indication:	For the treatment of frequent heartburn in adults 18 years of age and older.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207920

NDA APPROVAL

Pfizer, Inc.
Attention: Christine D. Chirdo
Director, U.S. Regulatory Strategy Category Lead
1 Giralda Farms
Madison, NJ 07940

Dear Ms. Chirdo:

Please refer to your New Drug Application (NDA) dated and received February 6, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium 24HR (esomeprazole) delayed-release tablets, 20 mg.

This NDA provides for the use of Nexium 24HR (esomeprazole) delayed-release tablets for the treatment of frequent heartburn in adults 18 years of age and older.

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.

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 identical to the 2-count immediate container (bottle), 2-count sample carton, 14-count immediate container (bottle), 14-, 28- and 42-count carton labels and 42-count "Club" carton with backer card label submitted on November 17, 2015 and 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 207920**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

After 6 months of marketing, delete the "New" graphic.

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.

We are waiving the pediatric study requirement for this application because the current position of the Agency is that heartburn in pediatric patients needs to be evaluated and treated by a physician.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

With regard to your proposal to evaluate intra- and inter-batch variability in the content uniformity of commercial batches, with an appropriate sampling plan across the compression run; and to implement additional controls if necessary after analysis of the data, we find your proposal acceptable. The updated sampling plan with supportive sample data will need to be submitted in the NDA Annual Report.

If you have any questions, call Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD
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
11/23/2015