Approval Package for:

APPLICATION NUMBER:

NDA 207920/S-002

**Trade Name:** Nexium® 24HR

**Generic or Proper Name:** Esomeprazole magnesium delayed-release tablet, 20 mg

**Sponsor:** Pfizer, Inc.

**Approval Date:** December 18, 2017

This “Changes Being Effected” (CBE-0) supplemental new drug application, 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.”
## Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Reviews / Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Other Action Letters</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>X</td>
</tr>
<tr>
<td>REMS</td>
<td></td>
</tr>
<tr>
<td>Summary Review</td>
<td></td>
</tr>
<tr>
<td>Officer/Employee List</td>
<td></td>
</tr>
<tr>
<td>Office Director Memo</td>
<td></td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
<td></td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td></td>
</tr>
<tr>
<td>Environmental Assessment</td>
<td></td>
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<tr>
<td>Pharmacology Review(s)</td>
<td></td>
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<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Microbiology / Virology Review(s)</td>
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<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
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<td>X</td>
</tr>
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<td>Risk Assessment and Risk Mitigation Review(s)</td>
<td></td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td></td>
</tr>
</tbody>
</table>
APPLICATION NUMBER:

NDA 207920/S-002

APPROVAL LETTER
Pfizer Inc.  
Attention: Nicola Romano  
Director, Regulatory Affairs NA  
Worldwide Regulatory Strategy  
One Giralda Farms  
Madison, NJ 07940  

Dear Mr. Romano:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 23, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium® 24HR (esomeprazole magnesium) delayed-release tablet, 20 mg.

This “Changes Being Effected” (CBE-0) supplemental new drug application, 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.

We remind you to remove the “See new warning” flag 6 months after the marketing start date.

**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 table below. The final printed labeling must also be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<table>
<thead>
<tr>
<th>Submitted Labeling</th>
<th>Submission Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-count sample bottle carton with peel back label</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>2-count immediate container (bottle)</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>14-count outer carton</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>14-count immediate container (bottle)</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>28-count (2x14-count) outer carton</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>42-count (3x14-count) outer carton</td>
<td>June 23, 2017</td>
</tr>
</tbody>
</table>
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 (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 207920/S-002.**” 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](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](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
12/18/2017
**DRUG FACTS**

**LABEL LOCATION (UNVARNISHED)**

**UNPRINTED AREA FOR DATE & LOT (UNVARNISHED)**

**PRINTED AREA FOR DATE & LOT (VARNISHED)**

**LASER CODING (VARNISHED)**

**128 CODE AREA - SUBSET C, 10 MIL DENSITY WITH 4 OR 6 DIGITS (CODE TO EXTEND TO EDGE OF FLAP - UNVARNISHED)**

**PRINTED SIDE OF CARTON**

**128 CODE = 090862**

**PRODUCTION**

(NO COLOR ACCURATE)

(b) (4)

---

Treats Frequent Heartburn

**DRUG FACTS TITLE**

**DRUG FACTS CONTINUED**

**HEADINGS**

**SUBHEADINGS/BODY TEXT**

**LEADING**

**# OF CHARACTERS PER INCH**

**BULLETS**

**SPACE BEFORE BULLET**

**BARLINES, HAIRLINES**

**SPACE BETWEEN HAIRLINES AND BOX END**

**TYPE SIZE**

9 pt

8 pt

8 pt

6 pt

6.5 pt

<39

5 pt

2 ems

1.5 pt, .5 pt

2 spaces

---

**Active ingredient (in each tablet) Purpose**

Esomeprazole 20 mg ................................... Acid reducer

(Each delayed-release tablet corresponds to 22.3 mg esomeprazole magnesium trihydrate)

**Uses**

- It treats frequent heartburn (occurs 2 or more days a week)
- Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**

**Allergy alert:**

- Do not use if you are allergic to esomeprazole

- Do not use if you have:
  - Trouble or pain swallowing food, vomiting with blood, or bloody or black stools
  - Heartburn with lightheadedness, sweating or dizziness
  - Chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
  - Frequent chest pain
- These may be signs of a serious condition. See your doctor.

**Ask a doctor before use if you have**

- Had heartburn over 3 months. This may be a sign of a more serious condition.
- Frequent wheezing, particularly with heartburn
- Unexplained weight loss
- Nausea or vomiting
- Stomach pain

**Ask a doctor or pharmacist before use if you are**

- Taking warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- Taking prescription antifungal or anti-yeast medicines
- Taking digoxin (heart medicine)
- Taking diazepam (anxiety medicine)
- Taking tacrolimus or mycophenolate mofetil (immune system medicines)
- Taking prescription antiretrovirals (medicines for HIV infection)
- Taking methotrexate (arthritis medicine)

**Stop use and ask a doctor if**

- Your heartburn continues or worsens
- You need to take this product for more than 14 days
- You need to take more than 1 course of treatment every 4 months
- You get diarrhea
- You develop a rash or joint pain

---

**Marketed by:** Pfizer, Madison, NJ 07940 USA

© 2017 Pfizer Inc.    Made in France

For most recent product information, visit www.Nexium24HR.com

Nexium is a registered trademark of AstraZeneca AB and is used under license.

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KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

---

Reference ID: 4197212
Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Directions

I for adults 18 years of age and older.
I this product is to be used once a day (every 24 hours), every day for 14 days.
I may take 1 to 4 days for full effect.

14-Day Course of Treatment
I swallow 1 tablet with a glass of water before eating in the morning.
I take every day for 14 days.
I do not take more than 1 tablet a day.
I swallow whole. Do not crush or chew tablets.
I do not use for more than 14 days unless directed by your doctor.

Repeated 14-Day Courses (if needed)
I you may repeat a 14-day course every 4 months.
I do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

If you are pregnant or nursing, ask a health professional before use.
Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Inactive ingredients:
corn starch, crospovidone, D&C red no. 27 lakes, FD&C blue no. 2, FD&C red no. 40 lakes, hydroxypropyl methylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, paraffin wax, polysorbate 80, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triethyl citrate.

Questions or comments? Call toll-free weekdays 9 AM to 5 PM at 1-866-226-1600.
Do not use if you have:

Allergy alert:
Do not use if you are allergic to esomeprazole.

Uses:
(esomeprazole magnesium trihydrate)

(Each delayed-release tablet corresponds to 22.3 mg
Esomeprazole 20 mg .....................................................................Acid reducer

Active ingredient (in each tablet) Purpose

Ask a doctor before use if you have

These may be signs of a serious condition. See your doctor.

Tips for Managing Heartburn

- Avoid foods or drinks that are
  some acidic fruits and vegetables.
  chocolate, caffeine, alcohol and even
  more likely to cause heartburn, such
  after eating.

- Do not eat late at night or just before
  • More likely to cause heartburn.
  • Eat slowly and do not eat big meals.

- Raise the head of your bed.
  • If you smoke, quit smoking.
  • If you are overweight, lose weight.

- If you develop a rash or joint pain
  • Do not take for more than 14 days or more often than every 4 months
  • Do not take more than 1 tablet a day
  • Take every day for 14 days
  swallow 1 tablet with a glass of water before eating in the morning

- If your heartburn continues or worsens
  • Do not use for more than 14 days unless directed by your doctor
  • Do not use if you are allergic to esomeprazole
  • Ask a doctor before use.

- Inactive ingredients
  polysorbate 80, sodium stearyl fumarate, sucrose, talc, titanium dioxide,

- Drug Facts
  read the directions and warnings before use

- Directions
  children under 18 years of age: ask a doctor before use. Heartburn in children
  may sometimes be caused by a serious condition.

14-Day Course of Treatment

• Do not eat late at night or just before
• Raise the head of your bed.
• If you smoke, quit smoking.
• If you are overweight, lose weight.
• Avoid foods or drinks that are
  • More likely to cause heartburn, such
  • Eat slowly and do not eat big meals.
• Raise the head of your bed.

- If you develop a rash or joint pain
  • Do not take for more than 14 days or more often than every 4 months
  • Do not take more than 1 tablet a day
  • Take every day for 14 days
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  polysorbate 80, sodium stearyl fumarate, sucrose, talc, titanium dioxide,

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• Do not eat late at night or just before
• Raise the head of your bed.
• If you smoke, quit smoking.
• If you are overweight, lose weight.
• Avoid foods or drinks that are
  • More likely to cause heartburn, such
  • Eat slowly and do not eat big meals.
• Raise the head of your bed.

- If you develop a rash or joint pain
  • Do not take for more than 14 days or more often than every 4 months
  • Do not take more than 1 tablet a day
  • Take every day for 14 days
  swallow 1 tablet with a glass of water before eating in the morning

- If your heartburn continues or worsens
  • Do not use for more than 14 days unless directed by your doctor
  • Do not use if you are allergic to esomeprazole
  • Ask a doctor before use.
APPLICATION NUMBER:

NDA 207920/S-002

OTHER REVIEW(S)
I. Background:

NDA 207-920 for Nexium® 24HR (esomeprazole magnesium, 20 mg) delayed-release tablets was approved as an OTC proton pump inhibitor on November 23, 2015, for the treatment of frequent heartburn (occurring 2 or more times per week) in adults 18 years of age and older. This application includes a 2-count immediate container (bottle), a 2-count sample carton with peel-back label, a 14-count immediate container (bottle), 14-, 28- (2x14 count) and 42-count (3x14 count) cartons and a 42-count (3x14) Clear Shell-Pack. Supplement 001, approved on February 3, 2017, is the most recently approved labeling for this product.

Supplement 002, submitted June 23, 2017, is a changes being effected (CBE-0) supplement in response to the Agency’s April 6, 2017 CBE supplement request letter. This letter notified the Sponsor of a mandatory safety related labeling change to inform consumers of risks of cutaneous and systemic lupus erythematosus events associated with the use of Proton Pump Inhibitors (PPIs). FDA requested that the Drug Facts labeling (DFL) be revised as described below. “Warnings” section of the Drug Facts labeling:
Following the subheading, “Stop use and ask a doctor if,” add the following bullet after the bullet that reads “you get diarrhea”:

- you develop a rash or joint pain

The labeling reviewed is the draft labeling submitted on June 23, 2017, and is compared to the labeling approved with supplement-001, approved on February 3, 2017.

<table>
<thead>
<tr>
<th>Submitted Labeling</th>
<th>Representative of Following SKUs</th>
<th>Submission Date(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-count sample bottle carton with peel back label</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>2-count immediate container (bottle)</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>14-count carton</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>14-count immediate container (bottle)</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>28-count (2x14-count) carton</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>42-count (3x14-count) carton</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>42-count (3x14-count) club carton, Clear Shell-Pack</td>
<td>N/A</td>
<td>June 23, 2017</td>
</tr>
</tbody>
</table>

II. Reviewer’s Comments
   A. 2-count sample, 14-, 28- (2x14-count), 42-count cartons (3x14-count) and 42-count (3-14-count) “Club” Clear-Shell Pack

   i. Outer Carton Label Outside Drug Facts

   a. For all cartons, except the 2-count sample bottle carton, a “See new warning” flag is added on the top left corner of the principal display panel (PDP).

   Comment: This is acceptable as it is truthful and not misleading. This statement is helpful to alert consumers of the new warning and does not interfere with other required information on the principal display panel.

   b. For the 42-count club carton, clear-shell pack, the “call toll free weekdays 9 AM to 5 PM EST at 1-866-226-1600” statement is moved from immediately below the “Questions or comments?” heading to immediately next to it.
Comment: This is acceptable as permitted in 21 CFR 201.66(d).

c. The copyright date on the “Marketed by: Pfizer, Madison, NJ 07940 USA” statement is changed from 2016 to 2017.

Comment: This is acceptable.

ii. Outer Carton Drug Facts Label

a. In the “Warnings” section, under the “Stop use and ask a doctor if” subsection, the following bulleted statement: “you develop a rash or joint pain” is added following the “you get diarrhea” statement.

Comment: This change is acceptable per the Agency’s CBE request letter on April 6, 2017.

b. For the 2-count sample bottle carton, the statement “If pregnant or breast-feeding, ask a health professional before use” is moved from the “Drug Facts (continued)” section to the peel back carton label immediately before the “Keep out of reach of children.” statement.

Comment: This is acceptable.

iii. Immediate Container (2- and 14-count bottle) labels

a. The copyright date in the “Marketed by: Pfizer, Madison, NJ 07940 USA” statement is changed from 2016 to 2017.

Comment: This is acceptable.

III. RECOMMENDATIONS

Issue an APPROVAL letter to the sponsor for the submitted Nexium 24HR delayed-release tablet labeling and request final printed labeling. The final printed labeling (FPL) must be identical to the following labeling:
### Submitted Labeling

<table>
<thead>
<tr>
<th>Submitted Labeling</th>
<th>Submission Date(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-count sample bottle carton with peel back label</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>2-count immediate container (bottle)</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>14-count carton</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>14-count immediate container (bottle)</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>28-count (2x14-count) carton</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>42-count (3x14-count) carton</td>
<td>June 23, 2017</td>
</tr>
<tr>
<td>42-count (3x14-count) club carton, Clear Shell-Pack</td>
<td>June 23, 2017</td>
</tr>
</tbody>
</table>

**IV. SUBMITTED LABELING**

The labels on the remaining pages of this labeling review were submitted and evaluated in this labeling review:

Following this page, 8 pages withheld in full - duplicate approved labeling

Reference ID: 4191244
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

YOON KONG
12/06/2017

KEVIN L LORICK
12/06/2017

I concur with the review and recommendations.
Filing Review for
Nexium® 24HR

SUBMISSION DATES: June 23, 2017

NDA/SUBMISSION TYPE: NDA 207920/supplement-002/CBE

ACTIVE INGREDIENTS: Esomeprazole magnesium, 20 mg

DOSAGE FORMS: Delayed-release tablets

SPONSOR: Pfizer, Inc.
Nicola Romano
Director, Regulatory Affairs, North America
(973) 660-5858

REVIEWER: Yoon Kong, Pharm.D., OND/ODEIV/DNDP

TEAM LEADER: Kevin L. Lorick, PhD, RAC, OND/ODEIV/DNDP

PROJECT MANAGER: Janice Adams-King, MSN, CPHN, CRNP,
OND/ODEIV/DNDP

Background:

Appears this way on original.
Nexium 24HR (esomeprazole magnesium 20 mg) delayed-release tablets, was approved as an OTC proton pump inhibitor on November 23, 2015, for the treatment of frequent heartburn (occurring 2 or more times per week) in adults 18 years of age and older. New drug application (NDA) approved labeling includes a 2-count immediate container (bottle), a 2-count sample carton with peel-back label, a 14-count immediate container (bottle), 14-, 28- (2x14 count) and 42-count (3x14 count) cartons and a 42-count (3x14) Clear Shell-Pack. Supplement 001, approved on February 3, 2017, is the most recently approved labeling and Drug Facts label for this product.

<table>
<thead>
<tr>
<th>Submitted Labeling</th>
<th>Representative of Following SKUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-count sample bottle carton with peel-back label</td>
<td>N/A</td>
</tr>
<tr>
<td>2-count immediate container (bottle)</td>
<td>N/A</td>
</tr>
<tr>
<td>14-count carton</td>
<td>N/A</td>
</tr>
<tr>
<td>14-count immediate container (bottle)</td>
<td>N/A</td>
</tr>
<tr>
<td>28-count (2x14 count) Carton</td>
<td>N/A</td>
</tr>
<tr>
<td>42-count (3x14 count) Carton</td>
<td>N/A</td>
</tr>
<tr>
<td>42-count (3x14 count) Club carton with backer card</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Issues</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the supplement correctly assigned as a PA, CBE0, CBE30?</td>
<td>Yes</td>
<td>CBE-0</td>
</tr>
<tr>
<td>Are the outer container and immediate container labels, and consumer information leaflet and other labeling included for all submitted SKUs?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>If representative labeling is submitted, does the submitted labeling represent only SKUs of different count sizes (same flavor and dosage form)?</td>
<td>N/A</td>
<td>None were submitted.</td>
</tr>
<tr>
<td>Is distributor labeling included?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Does the submission include the annotated specifications for the Drug Facts label?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Is Drug Facts title and Active ingredient/Purpose section of Drug Facts label visible at time of purchase?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Do any of the labels include “prescription strength” or similar statements?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Do any of the labels include “#1 doctor recommended” or similar endorsement statements?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Do any labels include text in a language other than English?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is a new trade name being proposed? If multiple trade names, is the primary or preferred trade name identified?</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
### Issues

<table>
<thead>
<tr>
<th>Issues</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does a medical officer need to review any clinical issues?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If SLR, should ONDQA also review?</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

**Reviewer’s Comments:** No issues are identified and no information requests are necessary at this time.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Yoon Kong
08/10/2017

Kevin L Lorick
08/14/2017

I concur with the review and recommendations