NDA 009170/S-040

APPROVAL LETTER

Bausch Health Us, LLC
Attention: Ashley Young
Associate Director, Global Regulatory Affairs, CMC
400 Somerset Corporate Blvd
Bridgewater, NJ 08807

Dear Mr. Young:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 13, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MYSOLINE (primidone) Tablets USP, 50 mg and 250 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes:

1. Addition of Bausch Health Companies, Inc. Steinbach, Manitoba, Canada [FEI # 3002806613] as an alternate site for the manufacture and of Mysoline (primidone tablets, USP) along with associated changes in the batch size and manufacturing process. This facility is also used for release and stability testing for the drug product.

2. Addition of (b) (4) as an alternate site for testing and release for the drug substance.

3. Addition of (b) (4) as alternate excipient testing facilities.

4. Revision to the drug substance release specification to remove solubility to comply with the USP monograph for primidone and to remove limits for residual solvents (b) (4) and (b) (4) to comply with official compendium USP Chapter <467>.

5. Provision of a risk assessment for elemental impurities in Mysoline Tablets as per the ICH Q3D guidance; the risk assessment supports non-testing of Mysoline

tablets, as manufactured at the Bausch Health Companies Steinbach, Manitoba facility for elemental impurities at release.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *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 "**Product Correspondence – Final Printed Carton and Container Labels**

for approved NDA 009170/S-040." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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