NDA 019962/S-050
NDA 019962/S-052

SUPPLEMENT APPROVAL

Toprol Acquisition LLC
Attention: Eilleen McCulloch
Senior Director, Regulatory Affairs
300 Tri-State International, Suite 272
Lincolnshire, IL 60069

Dear Mr. Anderson:

Please refer to your supplemental new drug applications (sNDAs) dated June 27, 2022, received June 29, 2022 (S-050), and dated and received February 24, 2023 (S-052), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Toprol XL (metoprolol succinate) controlled released Tablets.

These “Changes Being Effected” sNDAs provide for an editorial change to correct the appearance specification for the 200-mg tablet strength in Sections 3 and 16 of the prescribing information (PI) to 'A/mY" (S-050) and additional language about the risk of hypoglycemia. The following sections of the approved labeling were affected in supplement 50 (S-050):

- Highlights
- Warnings and Precautions (5.7)
- How Supplied/Storage and Handling
- Patient Counseling Information
- The manufacturer and distributor information was updated.

APPROVAL & LABELING

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. f the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

If you have any questions, please call Maryam Changi, Regulatory Project Manager, at (240) 402-2725.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Diretor for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
03/10/2023 02:36:06 PM