NDA 218698/S-002

APPROVAL LETTER

XTM Consulting LLC
Attention: Eric Schumacher
President
30 Lafayette Ave. Ste 1, # 1071
Morristown, NJ 07960

Dear Eric Schumacher:

Please refer to your Supplemental New Drug Application (sNDA) dated December 24, 2025, received December 29, 2025, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LOPRESSOR (metoprolol tartrate) tablets.

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

(a) The addition of a 60-count bottle presentation with a silica gel canister for the Metoprolol Tartrate Tablets, USP 12.5 mg in addition to the currently approved 30-count and 1000-count bottles.
(b) The addition of silica gel canisters to the currently approved 30-count and 1000-count bottle presentations.
(c) A change to (b) (4) HDPE bottles for all bottle counts (30, 60, and 1000) to enhance product stability and to suppress formation of (b) (4) impurities.
(d) The addition of new container closure component suppliers (bottles and caps).
(e) An updated Post-Approval Stability Protocol to include the 60-count presentation with a bracketing approach per ICH Q1D guidance.

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.

We note that your June 25, 2026, submission includes final printed labeling (FPL) for your patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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) 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 CONTAINER LABELS

We acknowledge your June 11, 2026, submission containing final printed carton and container labeling.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.[1]

If you have any questions, call Stephanie Ngan, Regulatory Business Process Manager, at (240) 402 - 5932.

Sincerely,

{See appended electronic signature page}

Joyce Crich, Ph.D.
Unit Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality

[1] https://www.uspnf.com/

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Joyce Crich

Digitally signed by Joyce Crich
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