NDA 205410/S-007

SUPPLEMENT APPROVAL

Eton Pharmaceuticals, Inc.
Attention: Adam Christensen
Vice President, Regulatory Affairs
21925 W. Field Parkway; Suite 235
Deer Park, IL 60010

Dear Adam Christensen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 13, 2026, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for HEMANGEOL (propranolol hydrochloride) oral solution.

This "Changes Being Effected" supplemental new drug application provides for conversion of the previously approved 50 mL professional sample presentation to a commercial presentation and to update labeling to reflect transfer of NDA ownership to Eton Pharmaceuticals, Inc. (No physical changes to DP).

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.

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).

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, contact Emma Gimose, Regulatory Business Process Manager, at (240) 402 - 1681 or emma.gimosse@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Nina Ni, Ph.D.
Supervisor
Division of Product Quality Assessment VII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling

Nina Ni

Digitally signed by Nina Ni
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