DEPARTMEET A HTU A D MA SERVICES e

ood and Drug Administration
Silv r Spring MD 20993

NDA 18716/S-028

O VAPPR A ETTER e

County Line Pharmaceuticals c/o Alvogen Group Inc. e
Attention: Patricia Jaworski, Vice President
Regulatory Affairs
10 Bloomfield Avenue, Building B
Pine Brook, NJ 07058

Dear Ms. Jaworski:

Please refer to your Supplemental New Drug Application (sNDA) dated October 26, 2015, received October 27, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Labetalol Hydrochloride Tablets.

We acknowledge receipt of your amendment dated April 25, 2016.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the reintroduction of the previously approved 500-count bottle configuration for Labetalol Hydrochloride Tablets, 100 and 200mg.

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you of your April 25, 2016 and April 27, 2016 commitments to implement the agreed upon revised labels in the next printing.

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 e labeling must be identical to the enclosed labeling package insert, 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for e this NDA, including CBE supplements for which FDA has not yet issued an action letter,

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with the content of labeling [1 CFR 14.5 (l)(1)(i)] in M S 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).

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ubmit final printed carton and immediate container labels that are identical to the immediate container labels submitted on April 5, 16, as soon as they are available, but no more than 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 (June 2008)*. Alternatively, you may submit 1 paper copies, with 6 of the copies individually mounted on heavy weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 18716/S-028**." Approval of this submission by FDA is not required before the labeling is used.

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Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the requirements for an approved NDA set forth 3 under 1 CFR 14.8 and 14.81.

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If you have any questions, call Yvonne Knight, Regulatory Project Manager, at (1) 796 1 . 3

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Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research 3

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