NDA 020215/S-027

SUPPLEMENT APPROVAL

ECI Pharmaceuticals LLC
C/O Attention: William Reightler
Regulatory Agent for ECI
514 North 12th Street
Allentown, PA 18102

Dear William Reightler:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 19, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Monoket (isosorbide mononitrate) tablets, 10 mg and 20 mg.

We also refer to our approval letter dated February 1, 2022, which contained the following error: issued in error to previous owner of NDA (incorrect recipient).

This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 1, 2022, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4) (FEI: (b) (4)) as an alternate analytical testing facility for excipients.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

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 Elizabeth Eydelman, MPH, Regulatory Business Process Manager, at (301) 796 - 5071.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Branch Chief, Branch 2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
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