NDA 020221/S-038

APPROVAL LETTER

Clinigen Healthcare Limited
c/o Mapi USA Inc.
Attention: Barbara Taylor, PhD
Senior Director, US Regulatory Affairs
2343 Alexandria Drive, Suite 100
Lexington, KY 40504

Dear Dr. Taylor:

Please refer to your Supplemental New Drug Application (sNDA) dated April 10, 2019 and received April 12, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ethyol (amifostine) for injection.

This Prior Approval supplemental new drug application provides for the following:

- Extension of drug product shelf life from 36 months to 48 months; and
- Revised assay and related substances test methods and drug product specifications and associated alternate testing sites.

APPROVAL

We have completed our review of this supplemental new drug 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 Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

Sincerely,

{See appended electronic signature page}

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

Ramesh Raghavachari

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