NDA 017422/S-062

**APPROVAL LETTER**

Emcure Pharmaceuticals Limited
c/o Heritage Pharmaceuticals Inc. d/b/a/ Avet Pharmaceuticals Inc.
Attention: Bernadette Attinger
One Tower Center Boulevard
Suite 1700
East Brunswick, NJ 08816

Dear Ms. Attinger:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 3, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BiCNU (carmustine) for injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for removal of the secondary packaging component, the Combi-kit guard, and its instruction guide.

**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 Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, PhD
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

Digitally signed by Ramesh Raghavachari
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