NDA 209606/S-005

APPROVAL LETTER

Celgene Corporation
Attention: Qing Wu
Manager, Regulatory Affairs
86 Morris Ave.
Summit, NJ 07901

Dear Mr. Wu:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 2, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for IDHIFA (enasidenib) tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the concentration of the sensitivity solution used in the HPLC-MS method for (b) (4) the drug substance.

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.
Branch Chief, B1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research