DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202714/S-012

APPROVAL LETTER

Onyx Pharmaceuticals, Inc., a wholly owned subsidiary of Amgen
Attention: Brian Stouch, RAC
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop 17-1-A
Thousand Oaks, CA 91320-1799

Dear Mr. Stouch:

Please refer to your Supplemental New Drug Application (sNDA) dated December 3, 2015, received December 3, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kyprolis™ (carfilzomib) for Injection, 60 mg.

We acknowledge receipt of your amendments dated February 3, 2016, May 24, 2016 and June 1, 2016.

This "Prior Approval" supplemental new drug application provides for the addition of 30 mg/vial strength and labeling changes to Package Insert along with new container and carton labels.

We have completed our review of this supplemental application, as amended. It is approved, with an expiry dating period of 36 months, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teicher Agosto, Regulatory Project Manager, at (240) 402-3777.

Sincerely,

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities 1
Office of Lifecycle Drug Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling