DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-602/S-018

Millennium Pharmaceuticals, Inc.
Attention: Marsha Marande, Ph.D.
Senior Manager, Regulatory Affairs
35 Landsdowne Street
Cambridge, MA 02139

Dear Dr. Marande:

Please refer to your supplemental new drug application dated November 21, 2008, received November 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Velcade® (bortezomib) for Injection, 3.5 mg.

We acknowledge receipt of your submissions dated March 17, 2009 and March 30, 2009.

Your submission of March 30, 2009 constituted a complete response to our March 24, 2009 action letter.

This "Prior Approval" supplemental new drug application provide for the addition of an alternate drug product manufacturer **(b) (4)** .

We completed our review of this supplemental new drug application, as amended. This supplement is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-602**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Tu-Van Lambert, Regulatory Project Manager, at (301) 796-4246.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel

4/24/2009 02:11:47 PM