DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-602/S-007

Millennium Pharmaceuticals, Inc
40 Landsdowne Street
Cambridge, MA 02139

Attention: Tanya Lewis, M.S.
Senior Manager
Regulatory Affairs

Dear Ms. Lewis:

Please refer to your supplemental new drug application dated June 8, 2005, received June 9, 2005, 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 submission dated July 22, 2005.

This "Changes Being Effected" supplemental new drug application provides a summary of the changes being implemented to the Package Insert that specifically strengthens the "PRECAUTIONS" section of the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 22, 2005.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 796-1332.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Acting Division Director
Division of Drug Oncology Products
Office of Oncology Products
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/

Robert Justice

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