DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-602/S-004

Millennium Pharmaceuticals, Inc.
40 Landsdowne Street
Cambridge, MA 02139

Attention: Renu Vaish, M.S.
Associate Director, Oncology Regulatory Affairs

Dear Ms. Vaish:

Please refer to your supplemental new drug application dated April 2, 2004, received April 5, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Velcade (bortezomib) for Injection 3.5mg.

We also refer to your April 13 and 29, 2004, amendments, received April 14 and 30, 2004, respectively.

This "Changes Being Effected" supplemental new drug application provides for changes to the package insert that specifically strengthen 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 draft labeling submitted on April 13, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-602/S-004." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Division Director
Division of Oncology Drug Products
Office of New Drug Evaluation 1
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/

Richard Pazdur

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