



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-602/S-013

Millennium Pharmaceuticals, Inc.  
Attention: Melody Brown  
Vice President, Regulatory Affairs  
40 Landsdowne Street  
Cambridge, MA 02139

Dear Ms. Brown:

Please refer to your supplemental new drug application dated December 11, 2006, received December 12, 2006, 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 January 26, March 30, April 19, June 12, and September 21, 2007.

This application includes updated labeling based on the results of a renal impairment study. We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 21 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved sNDA 21-602/S-013".

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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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

If you have any questions, call Tammie Brent, Regulatory Project Manager, at (301) 796-1409.

Sincerely,

*{See appended electronic signature page}*

Ramzi Dagher, MD  
Deputy Director  
Division of Drug Oncology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Ramzi Dagher  
10/10/2007 03:04:17 PM