DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021602/S-019 and S-020 **SUPPLEMENT APPROVAL**

Millennium Pharmaceuticals, Inc.
Attention: Margarita Aguilera, M.S., Senior Director Regulatory Affairs
35 Landowne Street
Cambridge, Massachusetts 02139

Dear Ms. Aguilera:

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Velcade (bortezomib) for Injection for the following:

NDA	S #	Letter date	Stamp date	Provides for	PDUFA date
021602	S-019	June 30, 2009	July 1, 2009	Revisions to the package insert to include dose recommendations in hepatic impairment – Post-Approval Commitment	May 1, 2010
021602	S-020	July 1, 2009	July 2, 2009	Revisions to the package insert to include Overall Survival data	January 2, 2010

We acknowledge receipt of your submissions dated September 25 (to S-019 and S-020), November 4, 2009 (to S-020) and December 11, 2009 (to S-019 and S-020).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 021602/S-019 and S-020**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the

proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Allison Adams-McLean, Regulatory Project Manager, at (301) 796-1381.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21602	SUPPL-19	MILLENNIUM PHARMACEUTICALS INC	VELCADE (BORTEZOMIB) INJ 3.5MG
NDA-21602	SUPPL-20	MILLENNIUM PHARMACEUTICALS INC	VELCADE (BORTEZOMIB) INJ 3.5MG

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

/s/

ALICE KACUBA
12/30/2009

ROBERT L JUSTICE
12/30/2009