



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

August 13, 2013

Melissa Anderson
Associate Director, Regulatory Affairs
Millennium Pharmaceuticals, Inc.
40 Landsdowne Street
Cambridge, MA 02139

Dear Ms. Anderson:

Your petition to the Food and Drug Administration request that the Agency require Fresenius's 505(b)(2) application (NDA No. 205004) for an injectable bortezomib formulation containing boric acid to be supported with the matters stated in the petition, was received by this office on 8/13/2013. It was assigned docket number FDA-2013-P-0998/CP1, and it was filed on 8/13/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an Agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Karen Kennard".

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)