



Food and Drug Administration  
Rockville MD 20857

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Re: Velcade  
Docket No.: 03E-0458

**FEB 25 2004**

The Honorable James E. Rogan  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,780,454, filed by Millenium Pharmaceuticals under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Velcade, the human drug product claimed by the patent.

The total length of the regulatory review period for Velcade is 1,723 days. Of this time, 1,610 days occurred during the testing phase and 113 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 26, 1998.

The applicant claims August 22, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 26, 1998, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: January 21, 2003.

FDA has verified the applicant's claim that the new drug application (NDA) for Velcade (NDA 21-602) was initially submitted on January 21, 2003.

3. The date the application was approved: May 13, 2003.

FDA has verified the applicant's claim that NDA 21-602 was approved on May 13, 2003.

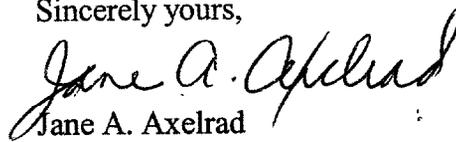
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Janice M. Klunder, Ph.D.  
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