



Food and Drug Administration
Rockville MD 20857

AUG 31 2004

Re: Kineret
Docket No.: 02E-0065

The Honorable Jon Dudas
Acting 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 Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,075,222, filed by Amgen, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Kineret, the human biological product claimed by the patent.

The total length of the regulatory review period for Kineret is 4,101 days. Of this time, 3,413 days occurred during the testing phase and 688 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 biologic product became effective: August 25, 1990.

The applicant claims August 23, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 25, 1990, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 28, 1999.

The applicant claims December 27, 1999, as the date the product license application (BLA) for Kineret (BLA 103950) was initially submitted. However, FDA records indicate that BLA 103950 was submitted on December 28, 1999.

3. The date the application was approved: November 14, 2001.

FDA has verified the applicant's claim that BLA 103950 was approved on November 14, 2001.

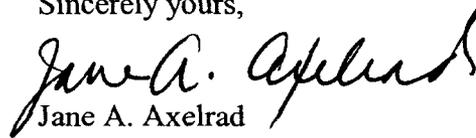
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

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: Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett, & Dunner, LLP
1300 I Street, NW
Washington, DC 20005-3315