DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Xigris
Docket Nos.: 02E-0099, 02E-0184, and 3E-0254

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 2327
Arlington, VA 22202

Dear Director Rogan:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 4,775,624; 5,681,932; and 5,270,040 filed by Eli Lilly & Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Xigris, the human biological product claimed by the patents.

The total length of the regulatory review period for Xigris is 2,493 days. Of this time, 2,193 days occurred during the testing phase, and 300 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: January 26, 1995.

   The applicant claims January 25, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 26, 1995, 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: January 26, 2001.

   FDA has verified the applicant's claim that the biological license application (BLA) for Xigris (BLA 125029/0) was initially submitted on January 26, 2001.

3. The date the application was approved: November 21, 2001.

   FDA has verified the applicant's claim that BLA 125029/0 was approved on November 21, 2001.

02E-0184

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This determination of the regulatory review period by FDA does not take into account the effective date of the patents, 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

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

cc: Brian P. Barrett
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