



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Alimta
Docket No.: 2004E-0307

The Honorable Jon Dudas
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

JAN _ 6 2006

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,344,932, filed by Eli Lilly and Company, 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 Alimta, the human drug product claimed by the patent.

The total length of the regulatory review period for Alimta is 4,166 days. Of this time, 4,038 days occurred during the testing phase and 128 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: September 10, 1992.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 10, 1992.

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: September 30, 2003.

The applicant claims September 29, 2003, as the date the new drug application (NDA) for Alimta (NDA 21-462) was initially submitted. However, FDA records indicate that NDA 21-462 was submitted on September 30, 2003.

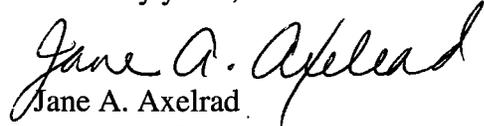
3. The date the application was approved: February 4, 2004.

FDA has verified the applicant's claim that NDA 21-462 was approved on February 4, 2004.

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,

A handwritten signature in cursive script that reads "Jane A. Axelrad".

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

cc: Elizabeth A. McGraw
Eli Lilly and Company
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