



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

Re: Erbitux  
Docket No.: 2005E-0254

JAN - 6 2006

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

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,217,866, filed by Aventis Pharmaceuticals, 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 Erbitux, the human biological product claimed by the patent.

The total length of the regulatory review period for Erbitux is 3,375 days. Of this time, 3,192 days occurred during the testing phase and 183 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: November 18, 1994.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 18, 1994.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: August 14, 2003.

The applicant claims August 12, 2003, as the date the product license application (BLA) for Erbitux (BLA 125084) was initially submitted. However, FDA records indicate that BLA 125084 was submitted on August 14, 2003.

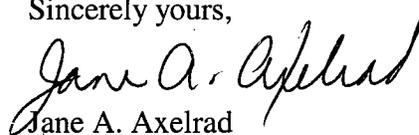
3. The date the application was approved: February 12, 2004.

FDA has verified the applicant's claim that BLA 125084 was approved on February 12, 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. § 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

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