



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Xolair
Docket No.: 2004E-0021

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. 6,267,958, filed by Genentech, 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 Xolair, the human biological product claimed by the patent.

The total length of the regulatory review period for Xolair is 3,440 days. Of this time, 2,329 days occurred during the testing phase and 1,111 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 20, 1994.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 20, 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: June 5, 2000.

The applicant claims June 2, 2000, as the date the product license application (BLA) for Xolair (BLA 103976/0) was initially submitted. However, FDA records indicate that BLA 103976/0 was submitted on June 5, 2000.

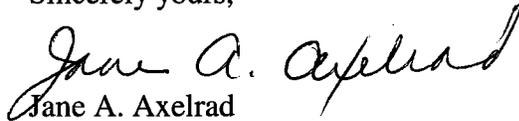
3. The date the application was approved: June 20, 2003.

FDA has verified the applicant's claim that BLA 103976/0 was approved on June 20, 2003.

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,

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: Jeffrey Kushan
Sidley, Austin, Brown & Wood, L.L.P.
1501 K Street, NW
Washington, DC 20005