

Food and Drug Administration
Rockville MD 20857Re: Daptacel
Docket No.: 03E-0251

JUN 23 2004

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. 5,667,787, filed by Aventis Pasteur, 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 Daptacel, the human biological product claimed by the patent.

The total length of the regulatory review period for Daptacel is 3,591 days. Of this time, 1,415 days occurred during the testing phase and 2,176 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: July 16, 1992.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 16, 1992.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: May 30, 1996.

The applicant claims May 29, 1996, as the date the product license application (BLA) for Daptacel (BLA 103666/0) was initially submitted. However, FDA records indicate that BLA 103666/0 was submitted on May 30, 1996.

3. The date the application was approved: May 14, 2002.

FDA has verified the applicant's claim that BLA 103666/0 was approved on May 14, 2002.

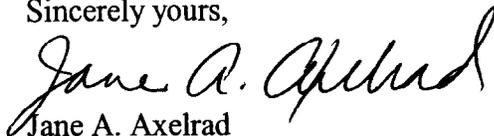
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

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

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