



AUG 31 2004

-- Re: Amevive
Docket No.: 03E-0260

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. 5,547,853, filed by Biogen, Inc., 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 Amevive, the human biological product claimed by the patent.

The total length of the regulatory review period for Amevive is 2,104 days. Of this time, 1,618 days occurred during the testing phase and 486 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: April 29, 1997.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 29, 1997.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: October 2, 2001.

FDA has verified the applicant's claim that the product license application (BLA) for Amevive (BLA 12536) was initially submitted on October 2, 2001.

3. The date the application was approved: January 30, 2003.

FDA has verified the applicant's claim that BLA 12536 was approved on January 30, 2003.

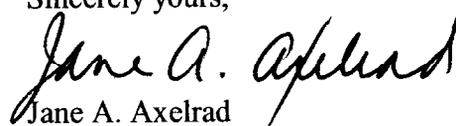
03E-0260

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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

cc: Louis Myers
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