



Food and Drug Administration  
Rockville MD 20857

5738 '04 JAN 21 22:31

Re: Extranaeal  
Docket No.: 03E-0248

The Honorable James E. Rogan  
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 15 2004

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,761,237, filed by Baxter International, Inc., 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 Extranaeal, the human drug product claimed by the patent.

The total length of the regulatory review period for Extranaeal is 2,207 days. Of this time, 1,478 days occurred during the testing phase and 729 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: December 6, 1996.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 6, 1996.

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: December 22, 2000.

FDA has verified the applicant's claim that the new drug application (NDA) for Extranaeal (NDA 21-321) was initially submitted on December 22, 2000.

3. The date the application was approved: December 20, 2002.

FDA has verified the applicant's claim that NDA 21-321 was approved on December 20, 2002.

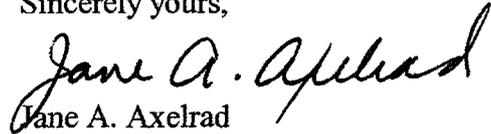
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Jane A. Axelrad". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

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

cc: Robert M. Barrett  
Bell, Boyd, & Lloyd, L.L.C.  
P.O. Box 1135  
Chicago, IL 60690-1135