



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

Re: Enablex  
Docket No.: 2005E-0249

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. 5,096,890, filed by Novartis International Pharmaceutical Ltd., 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 Enablex, the human drug product claimed by the patent.

The total length of the regulatory review period for Enablex is 3,824 days. Of this time, 3,073 days occurred during the testing phase and 751 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: July 6, 1994.

The applicant claims June 13, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 6, 1994, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 3, 2002.

The applicant claims December 30, 2002, as the date the new drug application (NDA) for Enablex (NDA 21-513) was initially submitted. However, FDA records indicate that NDA 21-513 was submitted on December 3, 2002.

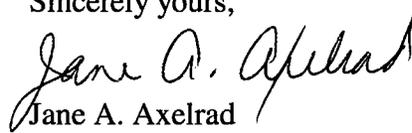
3. The date the application was approved: December 22, 2004.

FDA has verified the applicant's claim that NDA 21-513 was approved on December 22, 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. section 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: Edward J. Wilusz, Jr.  
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