

Food and Drug Administration
Rockville MD 20857Re: Ganirelix Acetate Injection (formerly Antagon)
Docket No.: 02E-0340

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

OCT 19 2004

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,801,577, filed by Syntex, 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 Ganirelix Acetate Injection (formerly Antagon), the human drug product claimed by the patent.

The total length of the regulatory review period for Ganirelix Acetate Injection is 3,558 days. Of this time, 3,376 days occurred during the testing phase and 182 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: November 2, 1989.

The applicant claims October 3, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 2, 1989, 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(b) of the Federal Food, Drug, and Cosmetic Act: January 29, 1999.

The applicant claims January 28, 1999, as the date the new drug application (NDA) for Ganirelix Acetate Injection (NDA 21-057) was initially submitted. However, FDA records indicate that NDA 21-057 was submitted on January 29, 1999.

3. The date the application was approved: July 29, 1999.

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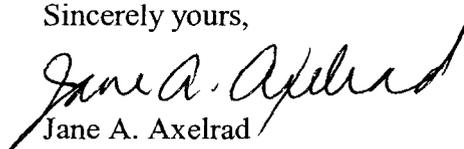
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FDA has verified the applicant's claim that NDA 21-057 was approved on July 29, 1999.

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: Herwig von Morze
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