

Food and Drug Administration
Rockville MD 20857

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Re: Ertaczo
Docket No.: 04E-0306

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

APR 8 2011

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,135,943, filed by Ferrer Internacional, S.A., 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 Ertaczo, the human drug product claimed by the patent.

The total length of the regulatory review period for Ertaczo is 2,718 days. Of this time, 1,914 days occurred during the testing phase and 804 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 3, 1996.

The applicant claims June 11, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 3, 1996, 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: September 28, 2001.

FDA has verified the applicant's claim that the new drug application (NDA) for Ertaczo (NDA 21-385) was initially submitted on September 28, 2001.

3. The date the application was approved: December 10, 2003.

FDA has verified the applicant's claim that NDA 21-385 was approved on December 10, 2003.

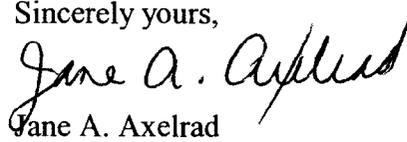
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

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

Sincerely yours,



Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research

cc: Marc S. Weiner
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