



Food and Drug Administration
Rockville MD 20857

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JAN 15 2004

Re: ORTHO-EVRA
Docket No.: 03E-0081

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. 5,876,746, filed by Johnson and Johnson, 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 ORTHO-EVRA, the human drug product claimed by the patent.

The total length of the regulatory review period for ORTHO-EVRA is 2,001 days. Of this time, 1,666 days occurred during the testing phase and 335 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: May 31, 1996.

The applicant claims May 30, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 31, 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 of the Federal Food, Drug, and Cosmetic Act: December 21, 2000.

FDA has verified the applicant's claim that the new drug application (NDA) for ORTHO-EVRA (NDA 21-180) was initially submitted on December 21, 2000.

3. The date the application was approved: November 20, 2001.

FDA has verified the applicant's claim that NDA 21-180 was approved on November 20, 2001.

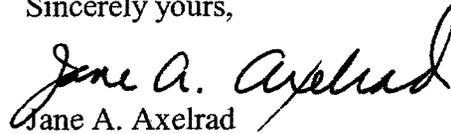
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad". The signature is fluid and cursive, with a large initial "J" and "A".

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

cc: Philip S. Johnson
Johnson & Johnson
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New Brunswick, NJ 08933