

Food and Drug Administration  
Rockville MD 20857

7 4 6 4 '03 JUL 21 09:41

Re: Benicar  
Docket No.: 02E-0339

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

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,616,599, filed by Sankyo Company, 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 Benicar, the human drug product claimed by the patent.

The total length of the regulatory review period for Benicar is 2,522 days. Of this time, 1,882 days occurred during the testing phase and 640 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: June 1, 1995.

The applicant claims May 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 1, 1995, 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: July 25, 2000.

FDA has verified the applicant's claim that the new drug application (NDA) for Benicar (NDA 21-286) was initially submitted on July 25, 2000.

3. The date the application was approved: April 25, 2002.

FDA has verified the applicant's claim that NDA 21-286 was approved on April 25, 2002.

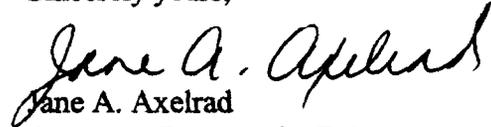
**02E-0339****LET 3**

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).

7 4 6 5 '03 JUL 21 09:41

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: Richard S. Barth, Esq.  
Frishauf, Holz, Goodman, & Chick, P.C.  
767 Third Avenue, 25th Floor  
New York, NY 10017-2023