DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

0129 7 DEC 17 A9:30 DEC 12 2007

Charles A. Weiss
Kenyon & Kenyon LLP
One Broadway
New York, NY 10004-1007

Re: Docket No. 2006P-0422/CP 1

Dear Mr. Weiss:

This letter responds to your citizen petition received on October 18, 2006, and submitted on behalf of KV Pharmaceutical Company (KV) (the Petition). In the Petition, you request that the Food and Drug Administration (FDA) (1) relist U.S. Patent 5,246,714 (the '714 patent) in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) for Toprol-XL (metoprolol succinate extended release) 100-milligram (mg) and 200-mg tablets, (2) refrain from approving any abbreviated new drug application (ANDA) for metoprolol succinate extended release 100- and 200-mg tablets until KV's 180-day exclusivity based on the '714 patent has expired, and (3) confirm that KV's right to 180-day exclusivity with regard to its ANDA No. 76-640 has not been affected by FDA's delisting of the '714 patent from the Orange Book.

The Petition is moot because the '714 patent has been relisted in the Orange Book, FDA has approved KV's ANDA No. 76-640, and FDA has recognized KV's eligibility for 180-day exclusivity for metoprolol succinate extended-release 100- and 200-mg tablets in its May 18, 2007, letter approving the ANDA. This 180-day exclusivity was based on KV's Paragraph IV certification to the '714 patent as well as other listed patents. Therefore your petition is denied as moot.

Sincerely,

/s/ Janet Woodcock

Janet Woodcock, M.D.
Acting Director
Center for Drug Evaluation and Research

2006P-0422

PDN 1