HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 11 2007

Food and Drug Administration
Rockville MD 20857

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

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

Dear Mr. Weiss: 1143 7 APR 16 A9:41

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 18, 2006, and submitted on behalf of KV Pharmaceutical Company (KV). Your petition requests that FDA (1) relist U.S. Patent 5,246,714 (the '714 patent) for Toprol-XL (metoprolol succinate extended release) 100-milligram (mg) and 200-mg tablets in FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book); (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.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

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

2006P-0422 LET 1