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John B. Dubeck  
Keller and Heckman LLP  
1001 G Street, N.W.  
Suite 500 West  
Washington, DC 20001

Re: Docket No. 2005P-0498/CP1

Dear Mr. Dubeck:

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 December 20, 2005, and submitted on behalf of Biovail Corporation. Your petition requests that the Agency require any applicant for an abbreviated new drug application (ANDA) for a generic version of Wellbutrin XL (bupropion hydrochloride extended-release tablets) to meet certain bioequivalence criteria. Specifically, you request that FDA require an ANDA applicant to (1) calculate and evaluate parameters in all of its bioequivalence trials based on concentrations of the parent drug and active metabolites, (2) conduct its bioequivalence trials at steady-state evaluating the performance of the dosage form based on the area under the plasma concentration versus time curve, the maximum drug concentration, and the minimum drug concentration, and (3) demonstrate that any generic formulation is bioequivalent to Wellbutrin (the immediate-release formulation of bupropion hydrochloride), Wellbutrin SR (the sustained-release formulation of bupropion hydrochloride), and Wellbutrin XL. Your petition also requests that FDA require any ANDA applicant to provide in vitro data demonstrating the absence of "dose dumping" if this extended-release dosage form is consumed with alcohol.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

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

2005P-0498

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