DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 2 2007

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Egros Fabrice, Pharm. D., Ph.D
President
UCB, Inc.
1950 Lake Park Drive
Smyrna, Georgia 30080

Docket No. 2006P-0405/CP1

Dear Dr. Fabrice:

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 October 3, 2006. You request that FDA take action to limit switches of antiepileptic drugs in stabilized patients who are well controlled, unless the switch is deemed medically necessary. Specifically, you request that FDA 1) require all antiepileptic drugs to include a warning to exercise extreme caution when switching those products, 2) include a discussion in the Orange Book of the risks associated with switching antiepileptic drugs, and 3) narrow its bioequivalence range for antiepileptic drugs.

FDA has been unable to reach a decision on your petition because it raises significant and 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 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-0405

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