DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 11 2007

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Derrick Mann
Caraco Pharmaceutical Laboratories, Ltd.
1150 Elijah McCoy Drive
Detroit, MI 48202

Re: Docket No. 2006P-0513/CP1

Dear Mr. Mann:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on December 14, 2006. Your petition requests that the Agency make a determination whether hydrochlorothiazide tablets, 100 mg, the subject of an abbreviated new drug application (ANDA) held by IVAX Pharmaceuticals Inc. (ANDA 85-022), were voluntarily discontinued from sale for reasons other than safety or effectiveness.

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-0513

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