DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 4 2007

Ken Phelps
President
Camargo Pharmaceutical Services, LLC
9825 Kenwood Road, Suite 102
Cincinnati, OH 45242

Re: Docket No. 2006P-0281/CP1

Dear Mr. Phelps:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated July 11, 2006. Your petition requests that FDA determine whether Orudis KT (ketoprofen) Tablets, 12.5 milligrams (NDA 20-429), held by Wyeth Consumer Healthcare, were withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your request because of 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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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

2006P-0281

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