Dockets

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 22 2006

Food and Drug Administration
Rockville MD 20857

Frederik Defesche
CUSTOpharm, Inc.
14413 American Kestrel Dr.
Austin, TX 78738

Re: Docket No. 2006P-0144/CP1

Dear Mr. Defesche:

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 March 30, 2006. Your petition requests that FDA determine that Delalutin (hydroxyprogesterone caproate) injection (new drug applications 10-347 and 16-911) was not withdrawn from sale for reasons of safety or effectiveness and therefore is suitable for submission in an abbreviated new drug application.

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-0144

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