DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 31, 2006

FILE COPY

Mr. Frederik Defesche
CUSTOpharm, Inc.
14413 American Kestrel Drive
Austin, Texas 78738

Dear Defesche:

Your petition requesting the Food and Drug Administration to make a determination that the discontinued Reference Listed Drug, Delalutin (Hydroxyprogesterone Caproate) Injection was withdrawn for safety and effectiveness reasons, and therefore is suitable for submission in an Abbreviated New Drug Application (ANDA), was received by this office on 03/30/2006. It was assigned docket number 2006P-0144 /CP 1 and it was filed on 03/30/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe

Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0144

ACK 1