



Food and Drug Administration
Rockville MD 20857

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AUG 15 2003

Dayton T. Reardan
Orphan Medical
13911 Ridgedale Drive, Suite 250
Minnetoka, Minnesota 55305

Re: Docket No. 03P-0039/CP1

Dear Mr. Reardan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on January 30, 2003. Your petition requests that the Agency revoke the policy regarding "in arrears" payment of user fees, establish a clear and fair waiver policy on user fees for orphan drug manufacturers, and move the management of the user fee waiver program back to the Office of the Commissioner where it formerly resided.

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 we have reached a decision on your request.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

03P-0039

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