DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 27 2013

Frances Duffy-Warren
Actelion Pharmaceuticals Ltd.
1820 Chapel Avenue West
Suite 300
Cherry Hill, NJ 08002

Re: Docket No. FDA-2013-P-0424

Dear Ms. Duffy-Warren:

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 April 8, 2013, submitted by Actelion Pharmaceuticals Ltd. Your petition requests that the Agency refrain from approving any abbreviated new drug application referencing Ventavis (iloprost) inhalation solution unless certain conditions are met.

FDA has been unable to reach a decision on your petition because it raises 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,

Carol Bennett

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