



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 8, 2013

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

Dear Dr. Duffy-Warren:

Your petition to the Food and Drug Administration to take actions described in the petition with respect to any abbreviated new drug application ("ANDA") that references the Actelion product, Ventavis® (iloprost) inhalation solution ("Ventavis"), was received by this office on 04/08/2013. It was assigned docket number FDA-2013-P-0424/CP1, and it was filed on 04/08/2013. 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 it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink that reads "Gloria Ortega".

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)