DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-779/S-008

Actelion, Ltd.
Attention Frances Dufy-Warren, Ph.D.
VP, U.S. Regulatory Affairs
1820 Chapel Avenue, West, Suite 300
Cherry Hill, NJ 08002

Dear Dr. Duffy-Warren:

Please refer to your supplemental new drug application dated July 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ventavis (iloprost) 10 mcg/1ml ampules and 20 mcg/2ml ampules Inhalation Solution.

We also acknowledge your submission dated August 8, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **PRECAUTIONS** and **POST MARKETING EXPERIENCE** sections of the labeling.

You proposed the following revisions:

1. The third paragraph in the **PRECAUTIONS/General** section has been changed from: "Ventavis has not been evaluated in patients with chronic obstructive pulmonary disease (COPD), severe asthma, or with acute pulmonary infections."

   To:

   "Ventavis inhalation can induce bronchospasm, especially in susceptible patients with hyperreactive airways. Ventavis has not been evaluated in patients with chronic obstructive pulmonary disease (COPD), severe asthma, or with acute pulmonary infections. Such patients should be carefully monitored during therapy with Ventavis."

2. The second paragraph in the **POSTMARKETING EXPERIENCE** section has been changed from: "Cases of epistaxis and gingival bleeding have been reported within one month of starting iloprost treatment."

   To:

   "Cases of bronchospasm and wheezing have been reported, particularly in susceptible patients with hyperreactive airways, such as patients with comorbid diseases affecting the airways (see **PRECAUTIONS**). Cases of epistaxis and gingival bleeding have been reported within one month of starting iloprost treatment. Cases of dizziness and diarrhea have also been reported with the use of Ventavis."

Other proposed revisions include minor editorial changes throughout the labeling.

We have completed our review of this application and it is approved, effective on the date of this letter for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on August 8, 2008.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call

Dan Brum Pharm.D., MBA
Regulatory Project Manager
(301) 796-0578

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Cc: Approved Label

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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