DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-290/S-012 **APPROVAL LETTER**

Actelion Clinical Research, Inc.
Attn: Frances Duffy-Warren, PhD
VP US Drug 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 August 3, 2007, received August 6, 2007, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tracleer (bosentan) 62.5 and 125 mg Tablets.

We acknowledge receipt of your submission dated March 27, 2009 which constituted a complete response to our February 27, 2009 action letter.

This supplemental new drug application provides for the use of Tracleer (bosentan) 62.5 and 125 mg tablets for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with WHO Class II to IV symptoms to improve exercise capacity and decrease clinical worsening. This supplement also complies with the requirements for content and format of labeling for human prescription drug and biological products (i.e., Physicians Labeling Rule [PLR]).

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

If you have any questions, please call Dan Brum, PharmD, RAC, Regulatory Project Manager, at (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

Enclosure: Agreed-upon labeling text

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

/s/

NORMAN L STOCKBRIDGE
08/07/2009