DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-081/S-001

Gilead Sciences, Inc.
Attention: Hansa Isokoski, MS, RAC
7575 West 103rd Ave.
Suite #102
Westminster, CO 80021-5426

Dear Ms. Isokoski:

Please refer to your supplemental new drug application (NDA) dated August 28, 2007 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Letairis (ambrisentan) 5 and 10 mg Tablets.

We also refer to your amendment dated October 17, 2007.

This supplemental new drug application provides for several changes to the RiskMAP. The changes include:

- changing the tasking of the monthly laboratory testing call from the RiskMAP Coordinating Center to the Specialty Pharmacies;
- changing "physician" and "doctor" to "prescriber" throughout the RiskMAP and supporting documents;
- modifications to the Patient Enrollment and Consent Form, including
  - requesting additional patient contact information to assist in the monthly patient contact;
  - updating of the privacy statement in response to the previous FDA comment;
  - simplification of the diagnosis section of the form;
- new patient reminder pieces (wallet card, refrigerator magnet, calendar stickers, white board, and patient checklist); and
- new LEAP introductory leaflet.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Health 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

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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