



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-081/S-004

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

SUPPLEMENT APPROVAL

Dear Ms. Isokoski:

Please refer to your supplemental new drug application dated April 29, 2008, received May 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Letairis (ambrisentan) 5 and 10 mg Tablets.

We also acknowledge receipt of your submission dated September 17, 2008.

This supplemental new drug application provides for revisions to the Medication Guide.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

In accordance with section 909(b)(1) of FDAAA, Letairis was identified as a product deemed to have in effect an approved Risk Evaluation and Mitigation Strategy (REMS) because the product had elements to assure safe use in effect on the effective date of Subtitle A. We received your proposed REMS on September 22, 2008. The Medication Guide approved with this supplement will be considered part of the REMS in accordance with 505-1. Under 21 CFR 208 and 505-1(e)(2) you are responsible for ensuring that the Medication Guide is available for distribution to patients who are dispensed Letairis.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-081/S-004.**"

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).

NDA 22-081/S-004

Page 2

If you have any questions, please call Dan Brum, PharmD, MBA 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: 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 Stockbridge
10/8/2008 04:36:46 PM