DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-128/S-001

Pfizer Inc.
Attention: Leilani Kapili
Director, Worldwide Regulatory Affairs and
Quality Assurance
50 Pequot Ave.
New London, CT 06320

Dear Ms. Kapili:

Please refer to your supplemental new drug application dated January 31, 2008, received January 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SELZENTRY™ (maraviroc) 150 mg and 300 mg tablets.

We acknowledge receipt of your submissions dated August 30, 2007, September 21, 2007, October 5, 2007, October 22, 2007, October 26, 2007, January 31, 2008, February 25, 2008, March 18, 2008, March 28, 2008, and November 20, 2008.

Your submission of January 31, 2008, constituted a complete response to our October 29, 2007, action letter.

This supplemental new drug application updates the package insert and patient package insert with the Week 48 data from Studies A4001027 and A4001028 for the traditional approval of SELZENTRY™ (maraviroc).

We 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 agreed-upon labeling text and patient labeling. 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(1) in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl/html that is identical to the enclosed labeling (text for the package insert and text for the medication guide). 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 22-128/S-001."**

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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

We approved this NDA (22-128/000) under the 21 CFR 314 Subpart H regulations for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills two postmarketing commitments (PMCc) made under 21 CFR 314.510, listed as PMC number 1 and 4 in the August 6, 2007 approval letter:

1. Submit Week 48 reports and datasets for Studies A4001027 and A4001028.

4. Submit Week 96 reports and datasets for Studies A4001027 and A4001028.

We remind you of your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA). The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81.

We also remind you of your postmarketing study commitment agreed to in your submission dated November 20, 2008. This commitment is listed below:

1. Conduct an in vivo drug interaction study with maraviroc and the P-glycoprotein substrate digoxin.

   Protocol Submission Date: November 30, 2009
   Final Report Submission Date: November 30, 2010

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Post marketing Study Commitment Protocol," "Postmarketing Study Commitment Final Report," or "Postmarketing Study Commitment Correspondence."**

Submit three copies of any introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Fisher Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, call Kenny Shade, Regulatory Health Project Manager, at (301)796-0807.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure (clean copy of 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/

Debra Birnkrant
11/25/2008 03:39:14 PM
NDA 22-128