CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-128

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-128

Pfizer Inc.
Attention: Leilani V. Kapili, MA
50 Pequot Avenue
New London, CT 06320

Dear Ms. Kapili:

Please refer to your new drug application (NDA) dated December 19, 2006, received December 20, 2006, 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 December 22, 2006, January 16, 2007, January 17, 2007, January 29, 2007 (2), February 5, 2007 (2), February 12, 2007, February 13, 2007, February 15, 2007, February 16, 2007 February 19, 2007, February 20, 2007, February 21, 2007 (2), February 22, 2007, February 23, 2007, February 27, 2007, February 28, 2007, March 1, 2007, March 2, 2007, March 7, 2007, March 12, 2007, March 13, 2007, March 20, 2007 (4), March 22, 2007 (3), March 23, 2007 (3), April 2, 2007, April 4, 2007, April 5, 2007, April 6, 2007, April 9, 2007 (2), April 12, 2007, April 19, 2007, April 27, 2007, April 30, 2007, May 1, 2007, May 4, 2007 (4), May 10, 2007 (2), May 11, 2007 (2), May 16, 2007, May 17, 2007 (2), May 21, 2007, May 22, 2007, May 24, 2007 (3), May 29, 2007, June 1, 2007, June 4, 2007 (2), June 5, 2007, June 12, 2007, and June 14, 2007 (2).

We completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit final printed labeling for the drug. The labeling should be identical in content to the enclosed labeling (text for the package insert). Submit final printed carton and container labels revised to include the trade name SELZENTRY.

In addition, we have determined that SELZENTRY (maraviroc) poses a concern related to hepatotoxicity. This concern requires development and distribution of a Medication Guide under 21 CFR 208 in order to prevent serious adverse effects, inform patients of information concerning risks that could affect their decision to use or continue to use the drug, and/or assure effective use of the drug. Therefore please submit a draft Medication Guide.

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material.

Submit revised 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.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

As required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of 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 proposed package insert directly to:

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

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with the Division of Antiviral Products to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Kenny Shade, Regulatory Project Manager, at (301) 796-0807.

Sincerely,

{See appended electronic signature page}

Edward Cox, MD, MPH
Acting Director,
Office of Antimicrobial Products
Center for Drug Evaluation and Research
Food and Drug Administration

Enclosure:

21 Page(s) Withheld

_____ Trade Secret / Confidential

_X_ Draft Labeling

_____ Deliberative Process

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

/s/

Edward Cox
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