DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-417/S-011

Critical Thearpeutics, Inc.
60 Westview Street
Lexington, MA 02412

Attention: Roberta Tucker, R. Ph.
Vice President, Regulatory Affairs and Quality Assurance

Dear Ms. Tucker:

Please refer to your supplemental new drug application dated March 31, 2005, received April 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyflo® (zileuton tablets).

We acknowledge receipt of your submissions dated: July 12, August 15, and September 1, 7, 14, and 26, 2005.

This supplemental new drug application provides for changes in synthesis, manufacturing and testing facilities, and specifications for drug substance and change in manufacturing and testing facilities for the drug product.

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 agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 1, 2005, copy enclosed, and, immediate container and carton labels submitted September 26, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-471/S-011**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the 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 Pulmonary and Allergy Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers 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 Anthony M. Zeccola, Regulatory Management Officer, at (301) 796-1318.

Sincerely,

{See appended electronic signature page}

Badrul Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Labeling

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

/s/

Badrul Chowdhury

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