DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-590 S-010

Avanir Pharmaceuticals
Attention: Randall Daye, MD, Vice President, Medical Affairs
101 Enterprise, Suite 300
Aliso Viejo, CA 92656

Dear Dr. Daye:

Please refer to your new drug application (NDA) dated September 26, 2006, received September 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fazaclo (clozapine) 12.5, 25, 50, and 100 mg Orally Disintegrating Tablets.

We acknowledge receipt of your submissions dated -

February 2, 2007 February 6, 2007 April 3, 2007

The February 2, 2007 submission constituted a complete response to our January 25, 2007 action letter.

This supplemental new drug application provides for product formulation changes that include a new container closure system and a new 12.5 mg tablet strength (labeling attached).

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

A 24 month expiry date is granted based upon the available stability data.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and immediate container labeling submitted September 26, 2006.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. 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 supplement NDA 21-590/S-010**".

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 this division 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

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 Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Thomas Laughren
5/30/2007 04:50:17 PM