DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-590

Alamo Pharmaceuticals, LLC
Attention: Neal R. Cutler, M.D.
President and Chief Executive Officer
8501 Wilshire Boulevard, Suite 318
Beverly Hills, CA 90211

Dear Dr. Cutler:

Please refer to your supplemental new drug application dated March 24, 2004, received March 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fazaclo (clozapine, USP) Orally Disintegrating Tablets.

We acknowledge receipt of your submission dated April 21, 2004.

This supplemental new drug application provides for revisions to the Fazaclo Patient Registry.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter.

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Russell Katz

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