DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-590 / SLR-001

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

Dear Dr. Cutler:

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

This supplemental new drug application provides for a new trade name which adds the suffix ODT (for Orally Disintegrating Tablets) to the previously approved trade name, Fazaclo.

- Previously approved trade name: Fazaclo (clozapine, USP) Orally Disintegrating Tablets.
- New trade name: FazaClo ODT (clozapine, USP) Orally Disintegrating Tablets abbreviated FazaClo ODT.

We completed our review of this application and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to that contained in the February 10, 2004, NDA approval letter and is to contain the new approved trade name FazaClo ODT.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. Approval of this submission by FDA is not required before the labeling is used.

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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