DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-590 / S-009

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

Dear Dr. Cutler:

Please refer to your supplemental new drug application dated December 19, 2005, received December 20, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FazaClo (clozapine, USP) Orally Disintegrating Tablets, 25 and 100 mg.

Reference is also made to the Orange Book, Application No. 019758, granting U.S. marketing exclusivity to Clozaril (clozapine) to treat patients with schizophrenia or schizoaffective disorder at risk for emergent suicidal behavior. Exclusivity for Clozaril for this indication expired on December 18, 2005.

This "Changes Being Effected" supplemental new drug application provides for the addition of the following indication to the FazaClo labeling:

> "FazaClo is indicated for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for reexperiencing suicidal behavior, based on history and recent clinical state."

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 19, 2005 (attached).

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 LT 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

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
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