DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-590 / S-008

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

Dear Dr. Cutler:

Please refer to your supplemental new drug application dated July 28, 2005, received July 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FazaClo (clozapine, USP) Orally Disintegrating Tablets.

This "Changes Being Effected" supplemental new drug application provides for a Black-Box Warning and Warnings Statements regarding increased mortality in elderly patients treated with atypical antipsychotic drugs for dementia-related psychosis.

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 July 28, 2005 (copy 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 CAPT Steven D. Hardeman, R.Ph., Acting Chief, Project Management Staff, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Acting 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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