



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-590 / S-007

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 May 17, 2005, received May \_\_, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FazaClo (clozapine, USP) Orally Disintegrating Tablets, 25 and 100 mg.

This "Changes Being Effected" supplemental new drug application provides for changes to the product labeling with the addition of new patient monitoring requirements for white blood cell and absolute neutrophil count testing.

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 May 17, 2005 (attached).

We request that you issue a letter communicating this important information about this drug product (i.e., a "Dear Health Care Professional" letter), and 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

Center for Drug Evaluation and Research

Office of New Drug Evaluation I

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Russell Katz

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