NDA 20-639/SLR-011/SLR-004/SLR-006

AstraZeneca Pharmaceuticals LP
Attention: Gerald L. Limp
Regulatory Affairs Director
P.O. Box 8355
Wilmington, DE 19803

27 MAR 2001

Dear Mr. Limp:

Please refer to your supplemental new drug application dated February 28, 2001, received March 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) tablets.

This "Changes Being Effected" supplemental new drug application provides for labeling changes as requested in our letter of September 25, 2000, specifically modification of labeling text to more clearly state that these agents are indicated for the treatment of schizophrenia.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted February 28, 2001). Accordingly, this supplemental application is approved effective on the date of this letter.

We have also reviewed the content of your supplements of April 1 and June 22, 1999, and note that these changes have either been incorporated or superceded by the approval of your supplement of February 28, 2001. Therefore, the above supplements will be retained in our files with no further action.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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,

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