DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639/S-020

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

Dear Mr. Limp:

Please refer to your supplemental new drug application dated January 22, 2004 and received January 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel® (quetiapine fumarate) Tablets. We also acknowledge receipt of your submission dated April 13, 2004.

This supplemental new drug application provides for changes to the package insert to add week 12 data from monotherapy studies for the treatment of acute manic episodes associated with Bipolar I Disorder.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled 'Providing Regulatory Submissions in Electronic Format – NDA". Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-639/S-020". Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit three copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising and Communications
HFD-42
Food and Drug Administration
Via Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Healthcare Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
Food and Drug Administration
Via Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Doris J. Bates, Ph.D., Regulatory Project Manager, at 301-594-2850.

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

Attachment: agreed-upon labeling (clean copy)

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
7/21/04 08:54:15 AM