



NDA 20-639 /S-016, S-017

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 applications dated December 30, 2002, received December 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel[®] (quetiapine fumarate) Tablets.

We also acknowledge receipt of your submissions dated November 11, and December 23, 2003.

Your submission of November 11, 2003 constituted a complete response to our October 27, 2003 action letter.

These supplemental new drug applications provide for the use of Seroquel[®] (quetiapine fumarate) tablets:

- As monotherapy in the treatment of acute manic episodes associated with Bipolar I disorder (S-016), and
- As adjunctive therapy with mood stabilizers (lithium or divalproex) in the treatment of acute manic episodes associated with Bipolar I disorder (S-017).

We completed our review of these applications, as amended, and they are approved effective on the date of this letter for use as recommended in the 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, these submissions should be designated "FPL for approved supplements

NDA 20-639/S-016, S-017.” Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that 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
5600 Fishers Lane
Rockville, MD 20857

Pediatric Post Marketing Commitment

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for neonates through 9 years of age and deferring pediatric studies for ages 10 to 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric studies under PREA for use as monotherapy and adjunct therapy for the short-term treatment of acute manic episodes associated with Bipolar I Disorder in pediatric patients ages 10 to 17.

Final Report Submission: February 11, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated “Required Pediatric Study Commitments”.

Please refer to the Agency’s Formal Written Request letter (b)(4)-----which the details of your pediatric development program were discussed for Seroquel”.

Superseded “Changes Being Effected” Labeling Supplements

Finally, we have reviewed the content of the following supplemental applications and note that the changes provided for have either been incorporated into the enclosed labeling text or have been further revised and incorporated into the enclosed labeling text. Therefore, these supplemental applications have been superseded and will be retained in our files with no further action.

	<u>Dated:</u>	<u>Received:</u>
S-018	June 13, 1986	July 21, 1987

This "Changes Being Effected" supplemental application provides for revision of the WARNINGS: Neuroleptic Malignant Syndrome (NMS) subsection and OVERDOSAGE section of labeling.

S-019	January 12, 1987	February 2, 1989
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This "Changes Being Effected" supplemental application provides for the addition of a subsection in the WARNINGS section of labeling entitled "Hyperglycemia and Diabetes Mellitus".

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, call Dr. Doris Bates, 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

Enclosure: Text for Package Insert

**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
1/12/04 10:28:48 AM