



NDA 21-436 / S-007

NDA 21-713 / S-004

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Susan H. Behling
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Behling:

Please refer to your supplemental new drug application (sNDA) dated May 14, 2004, received May 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets. Refer also to your sNDA dated February 15, 2005, received February 16, 2005 for Abilify (aripiprazole) Oral Solution.

We acknowledge receipt of your submission of February 15, 2005, which constituted a complete response to our action letter of November 2, 2004.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the OVERDOSAGE/Human Experience section of Abilify labeling as follows:

OVERDOSAGE

MedDRA terminology has been used to classify the adverse events.

Human Experience

A total of 76 cases of deliberate or accidental overdose with aripiprazole have been reported worldwide. These include overdoses with aripiprazole alone and in combination with other substances. No fatality was reported from these cases. Of the 44 cases with known outcome, 33 recovered without sequelae and one recovered with sequelae (mydriasis and feeling abnormal). The largest known acute ingestion with a known outcome involved 1080 mg of aripiprazole (36 times the maximum recommended daily dose) in a patient who fully recovered. Included in the 76 cases are 10 cases of deliberate or accidental overdose in children (age 12 and younger) involving aripiprazole ingestions up to 195 mg with no fatalities.

Common adverse events (reported in at least 5% of all overdose cases) reported with aripiprazole overdose (alone or in combination with other substances) include vomiting, somnolence, and tremor. Other clinically important signs and symptoms observed in one or more patients with aripiprazole overdoses (alone or with other substances) include acidosis, aggression, aspartate aminotransferase increased, atrial fibrillation, bradycardia, coma, confusional state, convulsion, blood creatine phosphokinase increased, depressed level of consciousness, hypertension, hypokalemia, hypotension, lethargy, loss of consciousness, QRS complex prolonged, QT prolonged, pneumonia aspiration, respiratory arrest, status epilepticus and tachycardia.

NDA 21-436 / SLR-007

NDA 21-713 / SLR-004

Page 2

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 15, 2005 (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 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

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/

Russell Katz
6/21/05 03:20:49 PM