



NDA 21-436 / S-013
NDA 21-713 / S-008
NDA 21-729 / S-001

Otsuka Maryland Research Institute
Attention: Kusuma Mallikaarjun, Ph.D.
Senior Director, Regulatory Affairs
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug applications dated and received June 30, 2005, submitted under section 505 of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets and Abilify (aripiprazole) Oral Solution.

Refer also to your supplement dated July 7, 2006, received July 10, 2006 for Abilify Discmelt (aripiprazole) Orally Disintegrating Tablets.

These supplemental new drug applications provide for revisions (under PRECAUTIONS: Drug-Drug Interactions) based on the results of two pharmacokinetic interaction studies (CN138126 and CN138127).

We have 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 submitted labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted July 7, 2006 – copy attached). Since the entire Abilify product line utilizes the same package insert, we request that you update the Abilify Injection NDA with the amended labeling information in your next annual report.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

NDA 21-436 / S-013

NDA 21-713 / S-008

NDA 21-729 / S-001

Page 2

If you have any questions, call Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.

Director

Division of Psychiatry Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

Enclosure (labeling)

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

Thomas Laughren
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