DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-436 / S-014
NDA 21-713 / S-009

Otsuka Pharmaceutical Co., Ltd.
Attention: Kusuma Mallikaarjun, Ph.D.
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug application dated July 6, 2005, received July 7, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets and Oral Solution.

Your submission of March 6, 2006 constituted a complete response to our February 19, 2006 action letter.

These supplemental new drug applications provide for labeling changes based on the results of study CN138113 (Phase IV commitment to investigate the effectiveness of doses lower than 10 mg in schizophrenia) to:

- Incorporate the efficacy findings from study CN138113 into the Clinical Trials section of labeling.
- Code reported (verbatim) adverse event terms to MedDRA terms.
- Incorporate adverse event data from study CN138113 into the listing entitled "Other Adverse Events Observed During the Premarketing Evaluation of Aripiprazole."
- Update labeled adverse event data in several sections based on information from the 7-30-04 Aripiprazole Clinical Summary of Safety.

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 February 19, 2006 – copy attached).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 21-436/S-014 and NDA 21-713/S-009**." Approval of these submissions by FDA is not required before the labeling is used.

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 LCDR Keith Kiedrow, 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
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