DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-436 / S-010
NDA 21-713 / S-006

Otsuka Maryland Research Institute, Inc.
Attention: Kusuma Mallikaarjun, Ph.D.
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug applications dated May 10, 2005, received May 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets and Oral Solution.

Your submissions of November 18, 2005, constituted a complete response to our action letter of August 18, 2005.

These "Changes Being Effected" supplemental new drug applications provide for a Boxed Warning and Bolded Warning section of the labeling concerning increased mortality in elderly patients with dementia-related psychosis. The submission also contains additional changes in the PRECAUTIONS, Use in Patients with Concomitant Illness, *Safety Experience in Elderly Patients with Psychosis Associated with Alzheimer's Disease* subsection of labeling.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 18, 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 LT 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

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
2/16/2006 02:23:31 PM