DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-436 S-017
NDA 21-713 S-012
NDA 21-729 S-004
NDA 21-866 S-004

Otsuka Pharmaceutical Company, Ltd.
Attention: Kusuma Mallikaarjun, Ph.D.
Senior Director, Regulatory Affairs
2440 Research Blvd.
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your March 23, 2007 supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ABILIFY (aripiprazole) Tablets, ABILIFY DISCMELT Orally Disintegrating Tablets, ABILIFY Oral Solution, and ABILIFY Injection FOR INTRAMUSCULAR USE ONLY.

Your submission of September 28, 2007 to NDA 21-436 and your cross reference submission of October 4, 2007 to NDAs 21-713, 21-729, and 21-866 constituted a complete response to our action letter of September 25, 2007.

These supplemental new drug applications provide for the use of Abilify for the treatment of schizophrenia in adolescents aged 13-17.

We have completed our review of these applications, as amended. These applications 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, text for the patient package insert).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission **"SPL for approved supplement NDA 21-436/S-017, NDA 21-713 S-012, NDA 21-729 S-004, NDA 21-866 S-004."**

Please refer to the requests made in the cover letter of your September 28, 2007 submission –

- We agree that individual or published case reports of serious occurrences of the subsumed adverse event terms will not need to be reported to the agency according to CFR 314.80 (c)(1)(i) Post Marketing 15 day "Alert Reports".
- We hereby grant a waiver for the half-page length requirement for the Highlights Section for the PLR format label on this sNDA and future sNDA submissions.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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).

If you have any questions, call Keith Kiedrow, PharmD, 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
10/29/2007 06:47:48 AM