DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 21-436/S-018
21-866/S-005
21-729/S-005
21-713/S-013

Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: Kusuma Mallikaarjun, Ph.D.
Sr. Director, Regulatory Affairs
2440 Research Blvd.,
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug applications dated May 16, 2007 (NDA 21-426/S-018), and August 28, 2007 (NDAs 21-866/S-005, 21-729/S-005, and 21-713/S-013), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) 5mg, 10mg, 15mg, 20mg and 30mg oral tablets (NDA 21-436), Abilify (aripiprazole) Injection 7.5mg/ml (NDA 21-866), Abilify (aripiprazole) Orally Disintegrating 5mg, 10mg, 15mg, 20mg and 30mg Tablets (NDA 21-729), and Abilify (aripiprazole) 1mg/ml in 50ml and 480ml oral solutions (NDA 21-713).

We acknowledge receipt of your submissions dated August 13, 2007, September 5, 2007 and September 6, 2007.

These supplemental new drug applications provide for the use of Abilify as an adjunctive treatment to treat patients with major depressive disorder.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed 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 supplements NDA 21-436/S-018, NDA 21-713/S-013, NDA 21-729 S-005, and NDA 21-866 S-005."**

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirements for both children and adolescents for these applications.

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 CDR Bill Bender, Regulatory Project Manager, at (301) 796-2145.

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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