DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21- 713

Otsuka America Pharmaceutical, Inc.
Attention: Kusuma Mallikaarjun, Ph. D.
Director, Regulatory Affairs/Abilify
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your new drug application (NDA) dated November 20, 2003, received November 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) 1 mg/ mL Oral Solution.

We acknowledge receipt of your submission of October 18, 2004, which constituted a complete response to our action letter of September 20, 2004.

This new drug application provides for an oral solution formulation of Abilify (aripiprazole). Abilify is indicated for the treatment of schizophrenia, and for the treatment of acute manic and mixed episodes associated with Bipolar Disorder.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted September 20, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-713**." Approval of this submission by FDA is not required before the labeling is used.

A 24 month expiry is granted for the drug product packaged in (b)(4) and stored in a refrigerator at 2°C to 8°C. Opened bottles stored in a refrigerator (2°C to 8°C) are granted a 6 month expiry.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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. As noted in our letter of September 20, 2004, we are waiving the pediatric study requirement for this application.

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

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Steven D. Hardeman, R. Ph., Senior Regulatory Project Manager, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Russell Katz, M. D.
Director
Division of Neuropharmacological Drug 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 this page is the manifestation of the electronic signature.

/s/

Russell Katz

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