DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-436 S-019, S-020, S-022
NDA 21-713 S-014, S-015, S-017
NDA 21-729 S-006, S-007, S-009
NDA 21-866 S-006, S-007, S-009

Otsuka Pharmaceutical Development & Commercialization, Inc.
Attn: Kusuma Mallikaarjun, Ph.D.
Senior Director, Regulatory Affairs
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug applications [sNDAs] submitted and received on July 11, 2007 [NDA 21-436 S-019, S-020] under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets.

Please also refer to your supplemental new drug applications [sNDAs] submitted August 28, 2007 and received on August 29, 2007 [NDA 21-713 S-014, S-015; NDA 21-729 S-006, S-007; and NDA 21-866 S-006, S-007] under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Oral Solution, Orally Disintegrating Tablet, and Injection for Intramuscular Use, respectively.

Please also refer to your labeling supplements NDA 21-436 S-022, NDA 21-713 S-017, NDA 21-729 S-009, and NDA 21-866 S-009, submitted December 27, 2007 and received December 28, 2007.

Please also refer to your amendments to NDA 21-436 S-019 and S-020, NDA 21-713 S-014 and S-015; NDA 21-729 S-006 and S-007; and NDA 21-866 S-006 and S-007, submitted on September 4, 2007, September 6, 2007, October 18, 2007, January 18, 2008, and March 19, 2008.

Your supplemental NDAs 21-436 S-019, 21-713 S-014, 21-729 S-006, and 21-866 S-006 provide for the use of Abilify as monotherapy in the acute treatment of bipolar disorder, manic or mixed, at a starting dose of 15 mg/day.

Your supplemental NDAs 21-436 S-020, 21-713 S-015, 21-729 S-007, and 21-866 S-007 provide for the use of Abilify as adjunctive therapy added to lithium or valproate in the short-term treatment of bipolar disorder, manic or mixed, again at a starting dose of 15 mg/day.

Your labeling supplements NDA 21-436 S-022, NDA 21-713 S-017, NDA 21-729 S-009, and NDA 21-866 S-009 provide for revision of the "Drug Interactions" section of labeling to state that aripiprazole has no clinically meaningful effect on the pharmacokinetics of lamotrigine.

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.

Content of Labeling: Structured Product Labeling [SPL]. the final printed labeling (FPL) must be identical to the enclosed labeling [package insert], and must be formatted in accordance with the requirements of 21 CFR 201.66.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed agreed-upon 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 NDA labeling under NDA 21-436 S-019, NDA 21-436 S-020, NDA 21-713 S-014, NDA 21-713 S-015, NDA 21-729 S-006, NDA 21-729 S-007, NDA 21-866 S-006, and NDA 21-866 S-007".

Pediatric Research Equity Act (PREA) Requirements: Phase 4 Commitments.
Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

With reference to NDA 21-436 S-019, NDA 21-713 S-014, NDA 21-729 S-006, and NDA 21-866 S-006, we are waiving the requirement for pediatric studies in all age groups, because:

A) necessary studies are impossible or highly impracticable. The pediatric starting dose of aripiprazole is 2 mg/day; this is titrated to 5 mg/day after 2 days and 10 mg/day after 2 more days. The target dose for pediatric patients is 10 mg/day. Therefore, study of a 15 mg starting dose in pediatric patients is not feasible.

With reference to NDA 21-436 S-020, NDA 21-713 S-015, NDA 21-729 S-007, and NDA 21-866 S-007, this product is now appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

There are no other Phase 4 commitments or Phase 4 requirements for any of these submissions.

"Dear Healthcare Professional" Letters.
If you issue a letter communicating important information about this product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to all four NDAs referenced above, with a copy to the following address:

MEDWATCH, HFD-410
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Introductory Promotional Materials.
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

Reporting Requirements. 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, please call Doris J. Bates, Ph.D., Regulatory Project Manager, at 301-796-1040.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling.

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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