DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 21-436/S-030, 21-866/S-017, 21-713/S-022, 21-729/S-015

SUPPLEMENT APPROVAL

Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: David Goldberger
Senior Director, Regulatory Affairs
100 Overlook Center, 1st Floor
Princeton, NJ 08540

Dear Mr. Goldberger:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 20, 2010 and received on October 21, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abilify (aripiprazole) tablet, oral solution, orally disintegrating tablet, and injectable formulation.

We also refer to our letter dated November 11, 2009 where we requested that a comprehensive Medication Guide be submitted incorporating all relevant safety information related to aripiprazole. Also reference is made to your submission dated May 11, 2010 where you submitted a Medication Guide for FDA review, and FDA's Complete Response letter dated August 6, 2010.

This Prior Approval supplement provides for revisions to the Medication Guide as we stated in our Complete Response letter dated August 6, 2010 and our email communication dated November 22, 2010. Based on our review of these supplemental applications they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

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, call Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

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:
Content of 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 P LAUGHREN
11/30/2010