DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 21436/S029, 21729/S014, 21713/S021, 21866/S016

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 (sNDA) dated and received April 16, 2010, submitted under section 505(b) of the Federal Food Drug, and Cosmetic Act (FDCA) for Abilify (aripiprazole) tablets 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg (NDA 21436), oral solution 1mg/ml (NDA 21713), orally disintegrating tablet 10 mg, 15 mg (NDA 21729), and injectable formulation 9.75 mg/1.3 mL single-dose vial (NDA 21866).

We acknowledge receipt of your submissions dated June 21, 2010, June 25, 2010, November 30, 2010, and January 26, 2011.

These Prior Approval supplemental new drug applications provide for the use of Abilify (aripiprazole) tablet, oral solution, orally disintegrating tablet, and injectable formulation for the maintenance treatment of bipolar I disorder as an adjunct to lithium or valproate.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

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 using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide). For administrative purposes, please designate this submission, **"SPL for approved sNDAs 21-436/S029, 21-729/S014, 21-713/S021, 21-866/S016."**

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.

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The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

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.

We are waiving the pediatric study requirement for ages 0 to 9 years because necessary studies are impossible or highly impracticable. This is because bipolar disorder cannot be reliably diagnosed in this age group, and therefore appropriate studies cannot be developed or carried out.

In addition, studies are completed in the 10-17 age group, given that we have adult data for adjunctive maintenance. Given that efficacy has been established for acute monotherapy treatment of manic and mixed episodes associated with bipolar I disorder in a population aged 10-17, in our judgment, adjunctive maintenance efficacy can be extrapolated to the 10-17 age group from the adult adjunctive maintenance study. Therefore, no additional pediatric studies are needed at this time.

PROMOTIONAL MATERIAL

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html;

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instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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

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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
02/16/2011

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