DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21436/S-038
NDA 21713/S-030
NDA 21729/S-022
NDA 21866/S-023

SUPPLEMENT APPROVAL

Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: David Goldberger, RPh, RAC
Vice President, Global Regulatory Affairs
2440 Research Blvd.
Rockville, MD 20850

Dear Mr. Goldberger:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received February 12, 2014 (NDA 21436/S-038), and April 3, 2014 (NDAs 21713/S-030, 21729/S-022, 21866/S-023), 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 1 mg/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 amendments dated March 7, 2014; March 26, 2014; April 30, 2014; June 10, 2014; June 20, 2014; June 26, 2014; August 29, 2014; October 28, 2014; November 14, 2014; November 24, 2014; December 2, 2014, December 8, 2014, and December 9, 2014.

Please also refer to our approval letter dated December 12, 2014. That letter contained an error in the "indications" sentence as described below:

Prior Statement: "These 'Prior Approval' supplemental new drug applications provide for labeling revisions based upon two adequate and well-controlled trials that demonstrate the efficacy for the new indication in pediatric patients with Tourette's Disorder."

Corrected Statement: "These 'Prior Approval' supplemental new drug applications provide for labeling revisions based upon two adequate and well-controlled trials that demonstrate the efficacy for the new indication in patients with Tourette's Disorder."

The effective approval date will remain December 12, 2014, the date of the original approval letter. The corrected labeling is unchanged.

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, 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, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 that includes labeling changes 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.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

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POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment agreed upon in your communication dated November 14, 2014:

2837-1 A controlled trial to evaluate the longer-term (i.e., maintenance) efficacy of aripiprazole in the treatment of pediatric patients (6-17 years) Tourette's Disorder. This trial must include a placebo group and more than one fixed dose and must utilize a randomized withdrawal design, following an adequate period of stabilization with open-label treatment of aripiprazole. Because it is important to establish the dose-response for maintenance, this trial should randomize patients on stable doses of aripiprazole and different doses of aripiprazole (and to placebo) during the maintenance phase.

The timetable you submitted on November 25, 2014, states that you will conduct this study according to the following schedule:

Final Protocol Submission: 01/31/2016
Trial Completion: 07/31/2021
Final Report Submission: 07/31/2022

Submit clinical protocols to your IND 116003 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to this postmarketing commitment should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

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
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

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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/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 CAPT William Bender, Senior Regulatory Project Manager, at (301) 796-2145 or via email at william.bender@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
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/

MITCHELL V Mathis
12/12/2014

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