



NDA 21436/S-040  
NDA 21713/S-031  
NDA 21729/S-023  
NDA 21866/S-025  
NDA 202971/S-008

## SUPPLEMENT APPROVAL

Otsuka Pharmaceutical Development & Commercialization, Inc.  
Attention: Dana Cahill, PhD  
Associate Director, Global Regulatory Affairs  
2440 Research Blvd.  
Rockville, MD 20850

Dear Dr. Cahill:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received January 8, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abilify (aripiprazole) 2, 5, 10, 15, 20, 30 mg tablets (NDA 21436); Abilify (aripiprazole) 1 mg/mL oral solution (NDA 21713); Abilify (aripiprazole) 10 and 15 mg Orally Disintegrating Tablets (NDA 21729); Abilify (aripiprazole) 9.75 mg/1.3 mL injection for IM use (NDA 21866); Abilify Maintena (aripiprazole) for extended-release injectable suspension, for intramuscular injection 300 mg/vial and 400 mg/vial (NDA 202971).

These “Changes Being Effected” supplemental new drug applications provide for the addition of pathological gambling and hiccups to section 6.2 Postmarketing Experience.

### **APPROVAL & LABELING**

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.

### **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).

### **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 email Simran Parihar, PharmD, Regulatory Health Project Manager, at [simran.parihar@fda.hhs.gov](mailto:simran.parihar@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, 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.**  
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/s/  
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MITCHELL V Mathis  
01/15/2016