



NDA 21436/S-36  
NDA 21713/S-28  
NDA 21729/S-20  
NDA 21866/S-21

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING  
REQUIREMENT**

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 (sNDAs) dated and received March 15, 2013, 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 amendment dated May 13, 2014.

The May 13, 2014, submission constituted a complete response to our March 24, 2014, action letter.

These "Prior Approval" supplemental new applications propose labeling revisions resulting from clinical trial CN138603, a maintenance trial in pediatric patients with irritability associated with autistic disorder. The study was conducted as a postmarketing requirement (#1570-1) as requested in our Agency letter dated November 19, 2009.

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, 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), 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).

### **FULFILLMENT OF POSTMARKETING REQUIREMENT**

We have received your submission dated March 15, 2013, containing the final report for the following postmarketing requirement listed in the November 19, 2009 letter.

1570-1            A deferred pediatric study under PREA for a maintenance treatment study to obtain long-term efficacy and safety data in patients ages 6-16 years.

We have reviewed your submission and conclude that the above requirement was fulfilled.

[This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our November 19, 2009, letter.](#)

### **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

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, email Simran Parihar, Pharm.D., 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.  
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.**  
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/s/  
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MITCHELL V Mathis  
06/09/2014