



NDA 207202

**NDA APPROVAL**

Otsuka Pharmaceutical Company, Ltd.  
Attention: Michael Fahmy, M.S.  
Director, Global Regulatory Affairs  
Otsuka Pharmaceutical Development & Commercialization  
508 Carnegie Center Drive  
Princeton, NJ 08540

Dear Mr. Fahmy:

Please refer to your New Drug Application (NDA) dated and received June 26, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify MyCite (aripiprazole tablets with sensor) 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg.

We acknowledge receipt of your amendment dated April 21, 2017, which constituted a complete response to our April 26, 2016, action letter.

This new drug application provides for the use of Abilify MyCite (aripiprazole tablets with sensor) to track drug ingestion of aripiprazole for the following indications:

- Treatment of schizophrenia
- Acute treatment of manic and mixed episodes associated with bipolar I disorder as monotherapy and as adjunct to lithium or valproate
- Maintenance treatment of bipolar I disorder as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of major depressive disorder

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We note that your November 13, 2017, submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

**WAIVER OF HIGHLIGHTS SECTION**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## **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). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

## **CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your November 13, 2017, submission containing final printed carton and container labels.

## **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.

This application triggers PREA because the use of the aripiprazole tablets with sensor is considered a new combination product. We note that for the drug alone, aripiprazole tablets, pediatric studies have been waived or fulfilled.

We are waiving the pediatric study requirement as described below because necessary studies are impossible or highly impracticable:

- Treatment of schizophrenia for ages birth to less than 13 years
- Treatment of bipolar I disorder for ages birth to less than 10 years
- Adjunctive treatment of major depressive disorder for ages birth to 6 years
- Treatment of irritability associated with autistic disorder for ages birth to less than 6 years

We are also waiving the pediatric study requirement for ages 7 to 17 years for the adjunctive treatment of major depressive disorder because Abilify MyCite is not likely to yield a meaningful therapeutic benefit over existing therapies for pediatric patients, and it is not likely to be used in a substantial number of pediatric patients.

We are deferring submission of your pediatric studies for this application as described below because this product is ready for approval for use in adults and the pediatric studies have not been completed:

- Treatment of schizophrenia for ages 13 to 17 years
- Treatment of bipolar I disorder for ages 10 to 17 years
- Treatment of irritability associated with autistic disorder for ages 6 to 17 years

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

3290-1 Conduct a human factors usability study using the to-be-marketed product in pediatric patients ages 13 to 17 years with schizophrenia, bipolar I disorder, and irritability associated with autistic disorder.

Final Protocol Submission: 12/2018  
Study Completion: 12/2021  
Final Report Submission: 12/2022

3290-2 Conduct a human factors usability study using the to-be-marketed product in pediatric patients with bipolar I disorder and irritability associated with autistic disorder ages 10 to 12 years and 6 to 12 years, respectively.

Final Protocol Submission: 12/2018  
Study Completion: 12/2021  
Final Report Submission: 12/2022

Submit the protocols to your IND 115927, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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, contact LT Brendan Muoio, Senior Regulatory Project Manager, at (240) 402-4518 or [brendan.muio@fda.hhs.gov](mailto:brendan.muio@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, MD  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosures:  
Content of Labeling  
Carton and Container 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  
11/13/2017