CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

207202Orig1s000

Trade Name:	Abilify MyCite
Generic or Proper Name:	aripiprazole tablets with sensor
Sponsor:	Osuka Pharmaceutical Company, Ltd.
Approval Date:	November 13, 2017
Indication:	• Treatment of adults with schizophrenia • Treatment of bipolar I disorder • Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate • Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate • Adjunctive treatment of adults with major depressive disorder (MDD)

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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:

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

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Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

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Build custom dashboards for your attorneys and clients with live data direct from the court.

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E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.