NDA 021436/S-044/S-045
NDA 202971/S-013
NDA 207202/S-002/S-004
NDA 021713/S-035/S-036
NDA 021729/S-027/S-028
NDA 021866/S-029/S-030

SUPPLEMENT APPROVAL

Otsuka Pharmaceutical Company, Ltd.
Attention: Dana Cahill, PhD
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 April 2, 2019 (NDA 207202/S-002), January 16, 2020 (NDAs 021436/S-044, 021713/S-035, 021729/S-027, 021866/S-029), January 28, 2020 (NDAs 021436/S-045, 021713/S-036, NDA 021729/S-028, 021866/S-030), and January 29, 2020 (NDAs 202971/S-013, 207202/S-004), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abilify (aripiprazole) tablets (NDA 021436), Abilify Maintena (aripiprazole) for extended-release injectable suspension (NDA 202971), Abilify MyCite (aripiprazole tablets with sensor) (NDA 207202), Abilify (aripiprazole) oral solution (NDA 021713), Abilify Discmelt (aripiprazole) orally disintegrating tablets (NDA 021729), and Abilify (aripiprazole) injection for intramuscular use (NDA 021866).

We acknowledge receipt of your amendment, submitted to NDA 021436/S-044, dated January 16, 2020, which constituted a complete response to our November 13, 2019, action letter.

NDAs 021436/S-045; 207202/S-004; 021713/S-036; 021729/S-087; 021866/S-030; 202971/S-013

We also refer to our letter dated December 5, 2019, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for aripiprazole. This information pertains to the risk of drug reaction with eosinophilia and systemic symptoms (DRESS).

These supplemental new drug applications provide for revisions to the labeling for aripiprazole consistent with our December 5, 2019, letter.

NDAs 021436/S-044; 207202/S-002; 021713/S-035; 021729/S-027; 021866/S-029

These supplemental new drug applications provide for the addition of the term "oculogyric crisis" in the Postmarketing Experience section of the Prescribing Information.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

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, call Ermias Zerislassie, Safety Regulatory Project Manager, at (301) 796-2770.

Sincerely,

{See appended electronic signature page}

Tiffany R. Farchione, MD
Director (Acting)
Division of Psychiatry
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TIFFANY R FARCHIONE
02/05/2020 12:21:33 PM