NDA 202971/S-017

APPROVAL LETTER

Otsuka Pharmaceutical Co Ltd
Attention: Onjee Choi, PhD
Associate Director, Global Regulatory Affairs
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Choi:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 7, 2024, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abilify Maintena (aripiprazole) for extended-release injectable suspension (aripiprazole extended release suspension for injection) injection.

We acknowledge receipt of your amendment dated January 24, 2025, which constituted a complete response to our January 7, 2025, action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for following:

- Replacement of manufacturer of sterile water for injection (SWFI) from (b) (4) (b) (4) (b) (4) which includes associated change in suppliers of the primary packaging components (b) (4) (b) (4) for SWFI by the proposed new manufacturer.
- Reduction of the fill volume of SWFI from 5 ml to 2.5 ml, including relevant labeling changes to reflect the proposed change.

APPROVAL & LABELING

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

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 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 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 via 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 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).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on January 24, 2025, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 202971/S-017.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teshara G. Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

Sincerely,

{See appended electronic signature page}

Vilayat Sayeed, Ph.D.
Division Director
Division of Product Quality Assessment II
Office of Product Quality Assessment I

Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

Vilayat Sayeed

Digitally signed by Vilayat Sayeed
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