



ANDA 216608

**ANDA APPROVAL**

Mylan Pharmaceuticals Inc.  
3711 Collins Ferry Road  
Morgantown, WV 26505  
Attention: Amy Martin  
Senior Director, Regulatory Affairs

Dear Amy Martin:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 20, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the tentative approval letter issued by this office on June 27, 2024, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Abilify Maintena for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, of Otsuka Pharmaceutical Company, Ltd. (Otsuka).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated February 10, 2022.

The RLD upon which you have based your ANDA, Otsuka's Abilify Maintena for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
8,338,427 (the '427 patent)	March 15, 2025
8,399,469 (the '469 patent)	June 29, 2025
10,525,057 (the '057 patent)	March 8, 2034
10,980,803 (the '803 patent)	September 24, 2033
11,154,553 (the '553 patent)	September 24, 2033
11,344,547 (the '547 patent)	September 24, 2033
11,400,087 (the '087 patent)	September 24, 2033
11,648,347 (the '347 patent)	April 6, 2034

Your ANDA contains paragraph IV certifications to each of the patents<sup>1</sup>, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial, under this ANDA. You have notified the Agency that Mylan Pharmaceuticals Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Mylan for infringement of the '427, '469, '057, '803, and '553 patents in the United States District Court for the District of Delaware [Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck v. Mylan Laboratories Ltd. and Mylan Pharmaceuticals Inc., Civil Action No. 22-00464]. Litigation was also initiated within the statutory 45-day period against Mylan for infringement of the '427, '469, '057, '803, and '553 patents in the United States District Court for the Northern District of West Virginia [Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck v. Mylan Laboratories Ltd. and Mylan Pharmaceuticals Inc., Civil Action No. 22-00032]. You have also notified the Agency that these cases were dismissed.

With respect to 180-day generic drug exclusivity, we note that Mylan was a first ANDA applicant for Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Mylan may be eligible for 180 days of generic drug exclusivity for Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Mylan failed to obtain tentative approval of its ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making

a formal determination at this time of Mylan's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Mylan begins commercial marketing of Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial, or (b) at any time prior to the expiration of the '427, '469, '057, '803, and '553 patents if Mylan has not begun commercial marketing. Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

We note that Mylan was granted a Competitive Generic Therapy (CGT) designation for Aripiprazole for Extended-Release Injectable Suspension, 300 mg/vial and 400 mg/vial, Single-Dose Vial. However, Mylan is not a "first approved applicant" for such competitive generic therapies, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act, because these drug products are eligible for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act. See section 505(j)(5)(B)(v)(III)(bb)(BB) of the FD&C Act. Therefore, these drug products are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

### **COMPENDIAL STANDARDS**

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>.

## **REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

*{See appended electronic signature page}*

For Edward M. Sherwood  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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<sup>1</sup> The Agency notes that the '547, '087, and '347 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.



John  
Ibrahim

Digitally signed by John Ibrahim

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