DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 206251

ANDA APPROVAL

Accord Healthcare Inc.
1009 Slater Road Suite 210-B
Durham, NC 27703
Attention: Sabita Nair
Senior Director, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Aripiprazole Tablets USP, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

Reference is also made to the complete response letter issued by this office on June 17, 2015, and to your amendments dated October 6 and December 4, 2015; February 3, April 11, May 24, June 20, August 31, October 18, October 28, and November 7, 2016.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the **ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Aripiprazole Tablets USP, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Abilify Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg of Otsuka Pharmaceuticals (Otsuka). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Otsuka's Abilify Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg, 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.S. Patent Number	Expiration Date
7,053,092 (the '092 patent)	January 28, 2022
8,017,615 (the '615 patent)	December 16, 2024*
8,580,796 (the '796 patent)	March 25, 2023*
8,642,600 (the '600 patent)	July 28, 2022*
8,642,760 (the '760 patent)	March 25, 2023*
8,759,350 (the '350 patent)	March 2, 2027
9,089,567 (the '567 patent)	January 28, 2022
9,125,939 (the '939 patent)	July 28, 2026
9,359,302 (the '302 patent)	September 25, 2022

9,387,182 (the ‘182 patent)	December 25, 2023 *with pediatric exclusivity added

With respect to the ‘615, ‘796, ‘760, ‘567 and ‘302 (excluding acute treatment of manic and mixed episodes associated with bipolar I disorder, adjunctive treatment of major depressive disorder, and treatment of irritability associated with autistic disorder) patents[1], your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Aripiprazole Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg, under this ANDA. You have notified the agency that Ajanta Pharma (Ajanta) complied with the requirements of section 505(j)(2)(B) of the FD&C Act.

With respect to the ‘092, ‘600, ‘350, ‘939, ‘182 and ‘302 (acute treatment of manic and mixed episodes associated with bipolar I disorder, treatment of major depressive disorder, and treatment of irritability associated with autistic disorder only) patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method of use patents that do not claim any indication for which you are seeking approval under your ANDA.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

[1] The agency notes that the ‘615, ‘796, ‘760, ‘567 and ‘302 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.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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