DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202971

NDA APPROVAL

Otsuka Pharmaceutical Company, Ltd.
c/o Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: David Goldberger, R.Ph., RAC
Senior Director, Regulatory Affairs
2440 Research Blvd.
Rockville, MD 20850

Dear Mr. Goldberger:

Please refer to your New Drug Application (NDA) dated September 26, 2011, received September 26, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ABILIFY MAINTENA (aripiprazole) for extended-release injectable suspension, for intramuscular (IM) injection 300 mg/vial and 400 mg/vial.

We acknowledge receipt of your amendments dated June 27, 2012, June 29, 2012 (2), July 3, 2012, July 5, 2012, July 17, 2012, July 18, 2012, July 25, 2012, August 2, 2012, August 31, 2012, September 21, 2012, October 23, 2012, February 14, 2013, and February 15, 2013.

The August 31, 2012, submission constituted a complete response to our July 26, 2012, action letter.

This new drug application provides for the use of ABILIFY MAINTENA (aripiprazole) for extended-release injectable suspension, for IM injection 300 mg/vial and 400 mg/vial for the treatment of schizophrenia.

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 February 14, 2013, 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.

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, Medication Guide, carton and container 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the immediate container labels submitted on February 15, 2013, 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 titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 202971**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.

We are waiving the pediatric study requirement for this application for all ages (ages 0-17) because the product fails to represent a meaningful therapeutic benefit and is unlikely to be used in a substantial number of patients for the management of maintenance treatment of schizophrenia. In addition, recruiting pediatric patients for a placebo-controlled maintenance

trial would be difficult. Schizophrenia is less common in children and adolescents than in adults. The onset of schizophrenia prior to 13 years of age is quite uncommon, with a prevalence estimated at 1 in 10,000 patients. The estimated prevalence in adolescents (ages 13 through 17 years) is about 0.5%. Compliance problems that make a depot formulation attractive in adults are less common in the pediatric population because medication is generally administered by a parent, guardian, or caregiver. Relapse and hospitalization rates are under 10% in children and adolescents with schizophrenia. Clinical practice guidelines for the treatment of schizophrenia in children and adolescents recommend the use of oral antipsychotics, with only limited use of depot preparations.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
02/28/2013