DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-866

Otsuka Maryland Research Institute
Attention: Kusuma Mallikaarjun, Ph.D.
Senior Director, Regulatory Affairs / Abilify
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your new drug application (NDA) dated November 29, 2005, received November 30, 2005, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) injection, 7.5 mg/mL.

We acknowledge receipt of your submissions dated January 10, 2006, January 30, 2006, May 9, 2006, May 11, 2006, May 25, 2006, July 13, 2006, August 7, 2006, and August 31, 2006. We also acknowledge receipt of your secure e-mail communications dated September 13, 2006 and September 18, 2006 in which you agreed to meet requested Phase 4 commitments.

This new drug application provides for the use of Abilify (aripiprazole) Injection in the treatment of agitation associated with schizophrenia or bipolar I disorder, manic or mixed.

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 attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed agreed-upon labeling. This includes text for the package insert, attached; immediate container labeling submitted July 13, 2006, pending the requested Phase 4 commitment below, and carton labeling submitted July 13, 2006, with revision as agreed in your secure e-mail message of September 13, 2006, to change the statement on the carton, so that it reads "It also contains tartaric acid, sodium hydroxide, and 150 mg/mL of sulfobutylether-ß-cyclodextrin." per 21 CFR 201.100(5)iii. These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-866**." Approval of this submission by FDA is not required before the labeling is used.

We note your request for categorical exclusion from the environmental assessment requirements, as per 21 CFR 25.31(b). We have reviewed your request, and it has been found acceptable.

The approved expiration date for this drug product is eighteen (18) months.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirements for this application, for both indications, as previously noted in our correspondence of January 4, 2006.

We remind you of the following postmarketing commitments [Phase 4 Commitments], agreed upon in your secure electronic communications of September 13, 2006 and September 18, 2006:

1. *Revision of immediate container label to provide a table of doses for practitioner reference.* In order to facilitate the proper I.M. dosing of aripiprazole injection, we have requested that you modify the immediate container label (vial label) to incorporate dosing information as presented in Table 6 of the proposed package insert. You have agreed to submit a proposal for modified vial labeling to include this information, or an explanation as to why the requested modification is not feasible.

   Since this is a Phase 4 commitment and prior approval of the labeling revisions [if feasible] will be required, we do not object to your using the presently submitted and approved vial labeling for product launch and up until such time as revised labeling [if feasible] is approved.

   Submission of proposal for modified vial labeling, or explanation as to why the requested modification is not feasible: On or before December 30, 2006.

2. *Submission of requested technical report for microbiology assessment.* We have requested that you submit Global Pharmaceutical Technology Report PT-337039-R-232, issued July 15, 2004, as a Phase 4 commitment for this NDA. Specifically, this report should provide the data which resulted from the subject drug product container-closure integrity testing. You have agreed to submit this information.

   Submission of report with requested data: On or before December 30, 2006.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, please call Doris J. Bates, Ph.D., Regulatory Project Manager at 301-796-2260, or contact her via secure electronic mail at doris.bates@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}
Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling [package insert]

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

/s/

Thomas Laughren
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