DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-729

Otsuka Pharmaceutical Co., Ltd.
Attention: Kusuma Mallikaarjun, Ph.D.
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your new drug application (NDA) dated and received December 22, 2003 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify Discmelt (aripiprazole orally disintegrating tablets).

Your submission dated December 12, 2005, and received December 13, 2005, constituted a complete response to our October 22, 2004, action letter.

This new drug application provides for the use of Abilify Discmelt (aripiprazole orally disintegrating tablets) for the treatment of schizophrenia and for the treatment of acute manic and mixed episodes associated with bipolar disorder.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the products with FPL that is not identical to the approved labeling text 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*. For administrative purposes, designate this submission "**FPL for approved NDA 21-729**." Approval of this submission by FDA is not required before the labeling is used.

A 24 month expiry date is granted based upon the available stability data.

With regards to regulatory test methods, the proposal for an interim specification of Q NLT (b)(4) in 30 minutes is acceptable. However, full dissolution profiles for at least (b)(4) tches or batches produced for 12 months, whichever comes first, should be provided and should also account for data indicating how many (b)(4) would be performed if the specification were to be set at Q NLT (b)(4) A final specificati---------- et after the data is provided and reviewed. This should be provided within 16 months of the date of this letter.

The Division of Medication Errors and Technical Support (DMETS) has recently reviewed your

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 requirement for this application.

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 Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures (DMETS recommendations and product labeling)

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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