



NDA 21-436 / S-001

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

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug application dated December 3, 2002, received December 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets.

We acknowledge receipt of your submissions of February 12, 2003, February 20, 2003, March 28, 2003, August 7, 2003, and August 12, 2003.

This supplemental new drug application (supplement) provides for the longer-term efficacy of aripiprazole in the treatment of schizophrenia.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (email of August 28, 2003).

Postmarketing Study Commitment

This supplement also provides for the fulfillment of the following post approval commitment:

- (Study 5)
Submit the results of Study CN138-047 (A Multicenter, Randomized, Double-Blind, Placebo Controlled, 26 Week Study Of A Fixed Dose Of Aripiprazole In The Treatment Of Stabilized Patients With Chronic Schizophrenia) to address the longer-term efficacy of aripiprazole in the treatment of adults with schizophrenia.

The above commitment has now been fulfilled.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-436 / S-001". Approval of this submission by FDA is not required before the labeling is used.

FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. Please refer to the Agency's Pediatric Written Request letter of February 11, 2003, for further details.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (labeling)

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

/s/

Russell Katz
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