DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 21-436/S-023, 21-713/S-018, 21-729/S-010, 21-866/S-010

Susan H. Behling
Director, Global Regulatory Strategy
Bristol-Myers Squibb Company
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Behling:

We acknowledge receipt of your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) tablets, Abilify Discmelt (aripiprazole) orally disintegrating tablets, Abilify (aripiprazole) oral solution, and Abilify (aripiprazole) injection dated February 13, 2008.

We additionally refer to e-mail communications from the Agency dated January 16, 2008 and January 23, 2008, requesting revisions to your prescriber labeling.

These new drug applications, submitted under "Changes Being Effected" provide for the following revisions to the Adverse Reactions-Extrapyramidal Symptoms-Dystonia section of labeling:

6 ADVERSE REACTIONS

6.2 Clinical Studies Experience

Dystonia

Class Effect: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

We note that you have incorporated our changes, verbatim, as requested in the aforementioned Agency communications.

We have completed our review of these applications, and they are approved, effective on the date of this letter.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDAs 21-436/S-023, 21-713/S-018, 21-729/S-010, 21-866/S-010." We expect that your February 13, 2008 labeling will be updated when submitted in SPL format to incorporate the revisions in the Agency approval letter dated February 27, 2008.

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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., Safety Regulatory Project Manager, at (301) 796-0532.

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

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

/s/

Mitchell Mathis
3/6/2008 03:06:12 PM
For Dr. Laughren