DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-731 S-048

Bristol-Myers Squibb Company
Attention: Marianne Frost
Associate Director, Global Regulatory Sciences
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Frost:

Please refer to your supplemental new drug application Dated May 17, 2007, received May 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BuSpar (buspirone HCl) tablets.

This "Changes Being Effected" supplement provides for the following labeling changes (additions underlined, deletions in strikethrough font):

Under Precautions --

Possible Concerns Related to Buspirone's Binding to Dopamine Receptors

Because buspirone can bind to central dopamine receptors, a question has been raised about its potential to cause acute and chronic changes in dopamine-mediated neurological function (eg, dystonia, pseudo-parkinsonism, akathisia, and tardive dyskinesia). Clinical experience in controlled trials has failed to identify any significant neuroleptic-like activity; however, a syndrome of restlessness, appearing shortly after initiation of treatment, has been reported in some small fraction of buspirone-treated patients. The syndrome may be explained in several ways. For example, buspirone may increase central noradrenergic activity; alternatively, the effect may be attributable to dopaminergic effects (ie, represent akathisia). ~~Obviously, the question cannot be totally resolved at this point in time. Generally, long-term sequelae of any drug's use can be identified only after several years of marketing.~~ **See ADVERSE REACTIONS: Postmarketing Experience.**

Under Adverse Reactions –

~~POSTINTRODUCTION CLINICAL EXPERIENCE~~ Postmarketing Experience

Postmarketing experience has shown an adverse experience profile similar to that given above. Voluntary reports since introduction have included rare occurrences of allergic reactions (including urticaria), angioedema, cogwheel rigidity, dizziness (rarely reported as vertigo), dystonic reactions (including dystonia), ataxias, extrapyramidal symptoms, dyskinesias (acute and tardive), ecchymosis, emotional lability, serotonin syndrome, transient difficulty with recall, urinary retention, ~~and~~ visual changes (including tunnel vision), parkinsonism, akathisia, restless leg syndrome, and restlessness.

Because of the uncontrolled nature of these spontaneous reports, a causal relationship to BuSpar treatment has not been determined.

Under How Supplied --

Store at ~~Room Temperature-Protect from temperatures greater than 86° F (30° C).~~ 25° C (77° F); excursions permitted between 15° C to 30° C (59° F to 86° F) [see USP controlled room temperature]. Dispense in a tight, light-resistant container (USP).

We have completed our review of this supplemental new drug application and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 17, 2007 (copy attached).

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, email CAPT Steven D. Hardeman, Chief Project Management Staff, at Steven.Hardeman@FDA.HHS.GOV.

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/

Thomas Laughren
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