DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-207/S-029

A Bristol-Myers Squibb Company
Attention: Liz Sagan-Graves
Associate Director, Global Pharmacovigilance and Labeling
P.O. Box 4500
Princeton, NJ 08543-4500

Dear Ms. Sagan-Graves:

We acknowledge receipt of your supplemental new drug application dated October 22, received October 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desyrel (trazodone hydrochloride) 50 mg, 100 mg, 150 mg, and 300 mg Tablets.

Reference is also made to an Agency letter dated August 27, 2003, requesting that you submit revisions to the Desyrel labeling as well as issue a "Dear Healthcare Practitioner" letter based upon the published medical literature for reports of possible interactions between trazodone and Norvir (ritonavir).

This supplement, submitted as a "Prior Approval" application, provides for labeling revisions as well as a "Dear Healthcare Practitioner" letter as requested in our August 27, 2003 Agency letter.

Specifically, the following labeling revisions have been:

1. Incorporate new subsections under the **CLINICAL PHARMACOLOGY** section entitled **Pharmacokinetics**, **Metabolism**, **Elimination**, and **Drug-Drug Interactions**.

2. The addition of a new paragraph to the **PRECAUTIONS-Drug Interactions** section.

3. Minor editorial changes to the **How Supplied** section.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your October 22, 2003 draft labeling. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert) submitted on October 22, 2003. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 18-207/S-029." Approval of this submission by FDA is not required before the labeling is used.

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, call Paul David, Senior Regulatory Project Manager, at (301) 594-5530.

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

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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