DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-726/S-006

Schwarz Pharma, Incorporated
Attention: Michelle Witt
Regulatory Affairs Manager
P.O. Box 2038
Milwaukee, WI 53201

Dear Ms. Witt:

We acknowledge receipt of your supplemental new drug application dated November 22, 2005, received November 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Niravam (Alprazolam) Orally Disintegrating Tablets (0.25 mg, 0.5 mg, 1 mg, and 2 mg).

This supplemental new drug application provides for revisions to the Precautions, Information to Patients subsection and the Dosage and Administration, Instructions to be Given to Patients for Use/Handling Niravam Tablets subsection to remove the statement that the ½ unused tablet should be discarded.

We have completed our review of this application. It is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). 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 an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-726/S-006**." Approval of this submission by FDA is not required before the labeling is used.

Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division, the Division of Psychiatry Products and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Susan E. Player, Regulatory Project Manager, at (301) 796-1074.

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
2/6/2006 12:28:01 PM