DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-726

Schwarz Pharma, Inc.
Attention: Gary M. Wieczorek
Manager, Regulatory Affairs
P.O. Box 2038
Milwaukee, WI 53201

Dear Mr. Wieczorek:

Please refer to your new drug application (NDA) dated December 19, 2003, received December 19, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Niravam™ (alprazolam) Orally Disintegrating Tablets.

We acknowledge receipt of your additional submissions dated:

March 19, 2004	May 21, 2004	August 17, 2004	October 22, 2004	December 23, 2004
March 25, 2004	June 7, 2004	September 3, 2004	November 18, 2004	January 14, 2005
March 30, 2004	July 15, 2004	September 14, 2004	November 22, 2004	
April 23, 2004	July 26, 2004	September 17, 2004	December 15, 2004	

The November 18, 2004 submission constituted a complete response to our October 19, 2004 action letter.

This new drug application provides for the use of Niravam (alprazolam) orally disintegrating tablets (ODTs) for Generalized Anxiety Disorder and Panic Disorder.

Labeling
We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and immediate container and carton labels submitted on January 14, 2005, received on January 19, 2005. Marketing the product(s) 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 NDA 21-726**." Approval of this submission by FDA is not required before the labeling is used.

Chemistry Manufacturing and Controls
We grant a 12 month expiry for the 0.25 mg and 0.5 mg alprazolam ODTs and a 24 month expiry for the 1 mg and 2 mg alprazolam ODTs.

Pediatric Research Equity Act (PREA)
Please refer to the Division's action letter dated October 19, 2004 in which the pediatric study requirement for this application was waived.

Postmarketing Commitment
We remind you of your postmarketing study commitment in your submission dated November 18, 2004. These commitments are listed below.

1. (b)(4)----------

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

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 Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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 Richardae C. Taylor, Pharm.D., Regulatory Project Manager, at (301) 594-2850.

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

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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