



ANDA 78-088

Kali Laboratories, Inc.
Attention: Laya Steve
Associate, Regulatory Affairs
400 Campus Drive
Somerset, NJ 08873

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 23, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Alprazolam Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg.

Reference is also made to your amendments dated March 3, 2006, June 30, 2006, August 15, 2006, August 30, 2006, October 6, 2006, December 6, 2006, January 8, 2007, April 30, 2007, May 1, 2007, and June 13, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved effective on the date of this letter. The Division of Bioequivalence has determined your Alprazolam Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Niravam Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg, respectively of Schwarz Pharma. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution Testing should be conducted using the FDA recommended method (USP Apparatus II (paddles) with 900 mL of a 70mM Potassium Phosphate Buffer at a pH of 6 at $37 \pm 0.5^{\circ}\text{C}$ and at a speed of 50 rpm.

The drug product should meet the following dissolution

specification for each strength of your Alprazolam Orally Disintegrating Tablets:

<u>Time</u>	<u>Dissolution</u>
10 min	NLT ---

The reference listed drug product (RLD) upon which you have based your ANDA, Schwarz Pharma's Niravam Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,024,981 (the '981 patent) and 6,221,392 (the '392 patent) are both scheduled to expire on April 9, 2018.

Your ANDA contains paragraph IV certifications to the '392 and '981 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of your Alprazolam Orally disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Kali Laboratories, Inc. (Kali) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. You have notified the agency that Kali Laboratories Inc. (Kali Labs) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Kali Labs within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Kali was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '981 and 392 patents. Therefore, with this approval, Kali is eligible for 180-days of generic drug exclusivity for Alprazolam Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Gary Buehler
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