DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-506

Kali Laboratories, Inc.
Attention: Kala Patel
Director, Regulatory Affairs
400 Campus Drive
Somerset, NJ 08873

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ondansetron Orally Disintegrating Tablets USP, 4 mg and 8 mg.

Reference is also made to our tentative approval letters dated June 17, and November 29, 2005; and to your amendments dated July 18, 2003; October 20, 2004;January 12, March 24, September 13, November 13 and December 6, 2006.

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 Ondansetron Orally Disintegrating Tablets, 4 mg and 8 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zofran ODT Orally Disintegrating Tablets, 4 mg and 8 mg, respectively, of GlaxoSmithKline (GSK). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, GSK’s Zofran ODT Orally Disintegrating Tablets, 4 mg and 8 mg, is subject to periods of patent protection. The following unexpired patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency’s publication titled Approved

Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,955,488 (the '488 patent)	May 14, 2016
6,063,802 (the '802 patent)	May 14, 2006

With respect to both of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ondansetron Orally Disintegrating Tablets USP, 4 mg and 8 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 was 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 complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Kali within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Kali was the first ANDA applicant for Ondansetron Orally Disintegrating Tablets USP, 4 mg and 8 mg, to submit a substantially complete ANDA with a paragraph IV certification to the '488 and '802 patents. Therefore, with this approval, Kali is eligible for 180-days of generic drug exclusivity for Ondansetron Orally Disintegrating Tablets USP, 4 mg and 8 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[2] 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.

[2] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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/

Robert L. West
12/26/2006 08:18:14 AM
for Gary Buehler