DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-475

APR 21 2005

Kali Laboratories, Inc.
Attention: W. Scott Groner
400 Campus Drive
Somerset, NJ 08873

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 9, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Tramadol Hydrochloride and Acetaminophen Tablets, 37.5 mg/325 mg.

Reference is made to the Tentative Approval letter issued by this office on September 22, 2004, and to your amendments dated November 7, 2003; August 10, October 1, and October 12, 2004; and March 15, and April 12, 2005.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Tramadol Hydrochloride and Acetaminophen Tablets, 37.5 mg/325 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Ultracet Tablets, 37.5 mg/325 mg, of Ortho McNeil Pharmaceutical, Inc. (Ortho). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

As noted in our Tentative Approval letter, Ultracet Tablets are subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent 5,336,691 (the '691 patent) is due to expire on August 9, 2011. Your application contains a paragraph IV patent certification under section 505(j)(2)(A)(vii)(IV) of the Act stating the '691 patent is invalid, or will not be infringed by your manufacture, use, or sale of Tramadol Hydrochloride and

Acetaminophen Tablets, 37.5 mg/325 mg, under this ANDA. We note that Ortho initiated a patent infringement suit against you, and that this suit initiated a 30-month period, identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application. This 30-month period has expired.

With this approval, Kali Laboratories Inc. (Kali) is also eligible for 180-day generic drug exclusivity for Tramadol Hydrochloride and Acetaminophen Tablets, 37.5 mg/325 mg. This is because the agency has determined that Kali was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '691 patent. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[1] will begin to run from the earlier of the date of first commercial marketing or of a court decision as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this application informing the agency of the date the exclusivity began.

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

Post-marketing reporting requirements for this abbreviated application 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
Division of Drug Marketing, Advertising, and
Communications (HFD-42)
5600 Fishers Lane
Rockville, MD 20857

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[1] Because your ANDA was filed before the date of enactment of the MMA 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).

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research