DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-500

Food and Drug Administration
Rockville MD 20857

SEP 6 2006

Ranbaxy Inc.
Attention: Abha Pant
Executive Director, Regulatory Affairs
600 College Road East
Princeton, New Jersey 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 28, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg (OTC).

Reference is also made to your amendments dated June 2, 2005; January 27, February 3, and March 16, 2006.

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 ANDA is **approved.** The Division of Bioequivalence has determined your Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg (OTC) to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug (RLD), Imodium® Advanced Caplets, 2 mg/125 mg (OTC), of McNeil Consumer & Specialty Pharmaceuticals, a Division of McNeil PPC, Inc. (McNeil). 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, McNeil's Imodium® Advanced Caplets, 2 mg/125 mg (OTC) is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,248,505 (the '505 patent)	September 28, 2010
5,612,054 (the '054 patent)	September 28, 2010
6,103,260 (the '260 patent)	July 17, 2017

Your ANDA contains paragraph IV certifications to each of the patents 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 Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg (OTC), 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 Ranbaxy Laboratories Limited (Ranbaxy) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. You have notified the agency that Ranbaxy complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of any of these patents was brought against Ranbaxy 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, Ranbaxy was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications for Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg (OTC). Therefore, with this approval, Ranbaxy is eligible for 180 days of generic drug exclusivity for Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg (OTC). 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 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
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,

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