ANDA 76-058 March 15, 2002

Ranbaxy Pharmaceuticals, Inc.
Attention: Abha Pant
U.S. Agent for: Ranbaxy Laboratories Limited
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 18, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Midazolam Hydrochloride Syrup, 2 mg (base)/mL.

Reference is also made to our Tentative Approval letter dated December 21, 2001, and to your amendment dated February 1, 2002, requesting final approval.

The reference listed product (RLD) upon which you have based your application, Versed Syrup of Hoffmann LaRoche, Inc. (Roche), is currently subject to a period of new dosage form (NDF) exclusivity. This exclusivity was extended until April 15, 2002, in accord with the pediatric exclusivity provisions of Section 505(A) of the Act. In a letter to the agency dated March 6, 2002, Roche stated that it waived its remaining exclusivity with respect to Versed Syrup.

We have completed the review of this abbreviated application 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 Midazolam Hydrochloride Syrup, 2 mg (base)/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Versed® Syrup, 2 mg (base)/mL, of Hoffmann La Roche Inc.). 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

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 FD-2253 at the time of their initial use.

Sincerely yours,

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