DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-239

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 13, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Zaleplon Capsules, 5 mg and 10 mg.

Reference is also made to your Tentative Approval letter dated November 25, 2005, and to your amendments dated June 24, 2005; and March 20, April 22, and May 28, 2008.

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 Zaleplon Capsules, 5 mg and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Sonata Capsules, 5 mg and 10 mg, respectively, of King Pharmaceuticals Research and Development, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug product (RLD) referenced in your application, Sonata Capsules, 5 mg and 10 mg, of King Pharmaceuticals, was subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" U.S. Patent No. 4,626,538 (the '538 patent) expired on June 6, 2008.

Your ANDA contains a paragraph III certification to the listed '538 patent under section 505(j)(2) (A)(vii)(III) of the Act. This certification states that TEVA Pharmaceuticals USA will not market Zaleplon Capsules, 5 mg and 10 mg, prior to the expiration of this patent. The agency recognizes that the '538 patent has expired, and that it no longer prevents the agency from approving your application.

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 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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Gary Buehler
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