DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091169

Teva Pharmaceuticals USA
Attention: Jean W. Zwicker
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 15, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Eszopiclone Tablets, 1 mg, 2 mg, and 3 mg.

Reference is also made to your amendments dated January 30, April 6, June 15, July 30, and December 3, 2009; January 19, February 3, April 1, May 14, October 12, and December 6, 2010; January 21, April 19, and May 13, 2011.

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 Eszopiclone Tablets, 1 mg, 2 mg, and 3 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lunesta Tablets 1 mg, 2 mg and 3 mg, respectively, of Sepracor Inc. 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, Sepracor's Lunesta Tablets, is subject to periods of patent protection. The following patents with their expiration dates 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
6,319,926 (the '926 patent)	January 16, 2012
6,444,673 (the '673 patent)	February 14, 2014
6,864,257 (the '257 patent)	August 30, 2012
7,381,724 (the '724 patent)	January 16, 2012

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Eszopiclone Tablets, 1 mg, 2 mg and 3 mg, under this ANDA. You notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '926, '673, '257, and '724 patents was brought against Teva within the statutory 45-day period in the United States District Court for the District of New Jersey [Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al., Civil Action No. 09-1302]. You also notified the agency of a consent judgment resulting in the dismissal of this case. This dismissal ends the 7½-year stay of approval, which had previously been in effect pursuant to sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the Act.

With respect to 180-day generic drug exclusivity, we note that Teva was a first applicant to submit a substantially complete ANDA with a paragraph IV certification for Eszopiclone Tablets, 1 mg, 2 mg, and 3 mg. Therefore, with this approval, Teva is eligible for 180-days of generic drug exclusivity for Eszopiclone Tablets, 1 mg, 2 mg and 3 mg. 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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U CM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

05/23/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.