DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078148

Anchen Pharmaceuticals, Inc.
Attention: Margaret L. Choy
Senior V.P., Regulatory Affairs
9601 Jeronimo
Irvine, CA 92618

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 18, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Zolpidem Tartrate Extended-release Tablets, 12.5 mg.

Reference is also made to your amendments dated May 11, October 27, November 22, and December 15, 2006; February 6, February 21, July 19, and September 26, 2007; February 22, March 14, July 8, July 16, and September 17, 2008; May 20, 2009; and April 21, May 5, May 19, May 21, May 26, June 2, June 4, June 7, August 12, September 14, October 1, November 9, and November 23, 2010. (b) (4)

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 Zolpidem Tartrate Extended-release Tablets, 12.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Ambien CR, 12.5 mg, of Sanofi Aventis US, LLC. (Sanofi). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in 500 mL of 0.01N HCl at 37°C using USP apparatus I (Basket) at 100 rpm. The test product should meet the following "interim" dissolution specifications:

Hour	Percent Dissolved
0.5	(b) (4)
1.5	
2	

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Sanofi's Ambien CR, 12.5 mg, is 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. 6,514,531 (the '531 patent) is scheduled to expire on June 1, 2020 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification to the '531 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Zolpidem Tartrate Extended-release Tablets, 12.5 mg, 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 was brought against Anchen Pharmaceuticals, Inc. (Anchen) for infringement of the listed '531 patent. This action must have been brought against Anchen prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Anchen complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Anchen 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 for Zolpidem Tartrate Extended-release Tablets, 12.5 mg, we note that Anchen

was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '531 patent. The agency notes that Anchen failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. We have determined, however, that this was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the ANDA was filed. Therefore, with this approval, the agency has determined that Anchen is eligible for 180 days of generic drug exclusivity for Zolpidem Tartrate Extended-release Tablets, 12.5 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

12/03/2010

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