DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-284

Anchen Pharmaceuticals, Inc
Attention: Margaret L. Choy
Vice President, Regulatory Affairs
5 Goodyear
Irvine, CA 92618

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 21, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Bupropion Hydrochloride Extended-release Tablets USP, (XL) 150 mg and 300 mg (Once Daily Dosing).

Reference is also made to your amendments dated May 16, 2005; June 23, July 7, August 9, 17, 18, 21 and 28, September 18, and October 2, 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 Bupropion Hydrochloride Extended-release Tablets USP, (XL) 150 mg and 300 mg (Once Daily Dosing) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Wellbutrin XL Extended-release of SmithKline Beecham Corp.

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

The dissolution testing should be conducted in 900 mL of 0.1 N HCl, at 37°C using USP Apparatus I(basket) at 75 rpm.

The test product should meet the following specifications:

2 hours: ≤ (b)(4)
4 hours: (b)(4)
8 hours: (b)(4)
16 hours: NLT (b)(4)

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when 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 reference listed drug (RLD) upon which you have based your ANDA, Wellbutrin XL Extended-release Tablets, 150 mg and 300 mg, of GlaxoSmithKline (GSK), is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,096,341 (the '341 patent) and 6,143,327 (the '327 patent) are both scheduled to expire on October 30, 2018.

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 Bupropion Hydrochloride Extended-release Tablets USP, (XL) 150 mg and 300 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 action is brought against Anchen Pharmaceuticals, Inc. (Anchen) for infringement of one or more of the patents that were the subjects of paragraph IV certifications. You notified the agency that Anchen complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '341 and '327 patents was brought against Anchen in the United States District Court for the Central District of California, Western Division [Biovail Laboratories, Inc., and SmithKline Beecham Corp. v. Anchen Pharmaceuticals, Inc., Civil Action No. CV-SACV04-1468]. You also notified the agency that the court dismissed the case with respect to the '327 patent, and decided that the '341 patent was not infringed. Therefore, under section 505(j)(5)(B)(iii) of the Act, your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Anchen was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '341 and '327 patents. Therefore, with this approval, Anchen is eligible for 180-days of generic drug exclusivity for Bupropion Hydrochloride Extended-release Tablets USP, (XL). 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,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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
12/14/2006 02:08:08 PM
for Gary Buehler