# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# ANDA 201374

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 201374

Anchen Pharmaceuticals, Inc.
Attention: David Quiggle
Director, Regulatory Affairs
9601 Jeronimo Road
Irvine, CA 92618

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 20, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lamotrigine Extended-release Tablets, 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg.

Reference is also made to your amendments dated January 6, April 17, June 5, July 27, August 9, September 20, October 15, November 13, and December 7, 2012.

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 Lamotrigine Extended-release Tablets, 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg , to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Lamictal XR Extended-release Tablets, 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg, respectively, of Smithkline Beecham Corporation.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The “interim” dissolution specifications are as follows:

Dissolution Method:

| | |
|---|---|
| Medium | Acid Stage (2 hours): 0.01M HCl<br>Buffer Stage: Phosphate Buffer, pH 6.8 + 0.5% SLS (Add 200 mL of 0.0205M sodium phosphate solution containing 2.25% w/v SLS to 700 mL of HCl) |
| Volume | Acid Stage: 700 mL; Buffer Stage: 900 mL |
| Apparatus | USP 2 (Paddle) |
| Speed | 50 rpm |

Specifications:

| Time (hr) | 25 mg and 200 mg | 50 mg | 100 mg | 250 mg | 300 mg |
|---|---|---|---|---|---|
| 2 | (b) (4) | | | | |
| 6 | | | | | |
| 10 | | | | | |
| 16 | | | | | |

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.

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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion 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/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

Gregory P. Geba, M.D., M.P.H.
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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ROBERT L WEST

12/26/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.