DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 091476

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) received on dated April 13, 2009, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluvoxamine Maleate Extended-release Capsules, 100 mg and 150 mg.[1]

Reference is also made to your amendments dated July 22, and September 2, 2009; May 24, June 16, and November 19, 2010; May 27, July 29, August 1 and 15, September 12 and 28, October 3 and 27, and December 15, 2011; and June 22, September 11, November 9, December 19 and 21, 2012. We also acknowledge receipt of your correspondence dated November 2, 2009; and September 2, and December 29, 2010, addressing patent issues associated with this ANDA.

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 Fluvoxamine Maleate Extended-release Capsules, 100 mg and 150 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Luvox CR of Jazz Pharmaceuticals, Inc. (Jazz).

[1] As originally submitted, this ANDA was for the 150 mg strength only. An amendment for the 100 mg strength was received on April 20, 2009.

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:

Medium:	pH 6.8 Phosphate Buffer
Volume:	900 mL
Apparatus:	II (Paddle)
Speed:	50 rpm
Temperature:	37°C ± 0.5°C

The test product should meet the following specifications:

2 hr:	NMT (b) (4)
4 hr:	(b) (4)
6 hr:	
8 hr:	NLT (b) (4)
12 hr:	NLT

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 RLD upon which you have based your ANDA, Luvox CR of Jazz, 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. 7,465,462 (the '462 patent), is scheduled to expire on May 10, 2020.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '462 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fluvoxamine Maleate Extended-release Capsules, 100 mg and 150 mg, under this ANDA. You have notified the agency that Anchen Pharmaceuticals, Inc. (Anchen) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Anchen for infringement of the '462 patent within the statutory 45-day period in the United States District Court for the Central District of California Western Division [Elan Pharma International Limited, and Jazz Pharmaceuticals, Inc. v. Anchen Pharmaceuticals, Inc. Anchen, Inc., Civil Action No. 8:09-cv-

01193-MRP-MLG], as well as in the United States District Court for the District of Delaware [Elan Pharma International Limited, and Jazz Pharmaceuticals, Inc. v. Actavis Elizabeth LLC, Anchen Pharmaceuticals, Inc. and Anchen Incorporated, Civil Action No. 1:09-cv-00744-GMS]. You have also notified the agency that both cases were dismissed.

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 for Fluvoxamine Maleate Extended-release Capsules, 100 mg and 150 mg. As a first applicant, Anchen was eligible for 180 days of generic drug exclusivity for both strengths. It is noted that neither strength was tentatively approved within the 30-month period described in section 505(j)(5)(D)(i)(IV). Nevertheless, the agency has determined that Anchen has not forfeited its eligibility for 180-day exclusivity with respect to the 150 mg strength.[2] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing date identified in section 505(j)(5)(B)(iv)(I). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

The Agency also has determined that Anchen has forfeited its eligibility for 180-day exclusivity with respect to the 100 mg strength because Anchen failed to obtain tentative approval of this strength within 30 months after the date on which the ANDA for these strengths was filed.[3] See section 505(j)(5)(D)(i)(IV) of the Act.

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[2] As noted above, ANDA 091476 for the 150 mg strength was received on April 13, 2009, and an amendment for the 100 mg strength was received on April 20, 2009. This ANDA was never tentatively approved, and therefore was not granted tentative approval for either strength within the 30-month periods described in section 505(j)(5)(D)(i)(IV): by October 13, 2011 (150 mg strength) and by October 20, 2011 (100 mg strength). Nevertheless, with respect to the 150 mg strength, the agency has determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed. Specifically, there were revisions in the labeling of the RLD that necessitated changes in Anchen's labeling that were not resolved until October 18, 2011, which is after the 30-month forfeiture date for the 150 mg strength.

[3] The agency has determined that the changes in the requirements for approval related to the RLD labeling revisions were not a cause of Anchen's failure to obtain tentative approval of the 100 mg strength within the 30-month period relevant to the 100 mg strength because those issues were resolved prior to October 20, 2012.

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(s) 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

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

03/13/2013

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