DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 201951



Actavis Elizabeth LLC
Attention: Janak Jadeja, R.Ph.
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on September 16, 2010, accepted for filing on September 16, 2010, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Doxepin Tablets, 3 mg and 6 mg.

Reference is also made to your amendments dated September 10, and September 16, 2010; February 17, September 6, September 29, and December 15, 2011; and January 12, April 27, May 15, June 1, July 31, and September 18, 2012. We also acknowledge receipt of your correspondences dated November 2, November 29, December 21, and December 22, 2010; March 29, March 30, and April 7, 2011; and February 19, 2013, 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 Doxepin Tablets, 3 mg and 6 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Silenor Tablets, 3 mg and 6 mg, respectively, of Pernix Therapeutics LLC (Pernix). 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, Pernix's Silenor Tablets, is subject to unexpired periods of patent protection.

The following patents and 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 |
|---|---|
| 5,585,115 (the '115 patent) | January 9, 2015 |
| 5,725,884 (the '884 patent) | January 9, 2015 |
| 5,866,166 (the '166 patent) | January 9, 2015 |
| 5,948,438 (the '438 patent) | January 9, 2015 |
| 6,103,219 (the '219 patent) | January 9, 2015 |
| 6,211,229 (the '229 patent) | February 17, 2020 |
| 6,217,909 (the '909 patent) | January 9, 2015 |
| 7,915,307 (the '307 patent) | August 24, 2027 |

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Doxepin Tablets, 3 mg and 6 mg, under this ANDA. You have notified the agency that Actavis Elizabeth LLC (Actavis) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Actavis for infringement of the '229 and '307[1] patents within the statutory 45-day period in the United States District Court for the District of Delaware [Somaxon Pharmaceuticals, Inc. and Procom One, Inc. v. Actavis Elizabeth LLC, et al., Civil Action No. 10-1100]. Litigation was subsequently dismissed.

With respect to 180-day generic drug exclusivity, we note that Actavis was a first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Silenor Tablets, 3 mg and 6 mg. Therefore, with this approval, Actavis is eligible for 180 days of generic drug exclusivity for Doxepin Tablets, 3 mg and 6 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.

[1] The agency notes that your patent certification to the '307 patent was submitted in an amendment to your ANDA.

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.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to

self-identify or pay facility fees are subject to being denied entry into the United States.

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}*

Kathleen Uhl, M.D.
Acting 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

07/26/2013

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.