DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077302

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg (Mixed Salts of a Single Entity Amphetamine Product).

Reference is also made to your amendments dated March 30, May 31, July 12, July 14, August 4, and September 9, 2005; September 21, 2007; August 21, 2008; March 9, June 12, June 24, July 8, August 4, and December 15, 2009; January 26, and March 24, 2010; March 11, May 2, August 19, September 29, and December 9, 2011; and February 3, February 15, and April 16, 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 Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Adderall XR Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg, respectively, of Shire Development, Inc. (Shire).

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:

Medium	0.1N Hydrochloric Acid
Volume	900 mL
USP Apparatus	Type 1 (basket)
Rotation (rpm)	100 rpm

Specifications:

Time	Percent Dissolved
30 Minutes	(b) (4)
2 Hours	
6 Hours	

The "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, Shire's Adderall XR Capsules, is subject to periods of patent protection. The following patents and their expiration dates (with pediatric exclusivity added) 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
6,322,819	April 21, 2019
6,605,300	April 21, 2019
RE41,148	April 21, 2019
RE42,096	April 21, 2019

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 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 all litigation with respect to these patents has been dismissed.

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.

We 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 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

06/22/2012

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