DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200881

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) dated December 29, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 mg.

Reference is also made to your tentative approval letter dated June 29, 2012, and your amendment dated July 12, 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 Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Intuniv Extended-release Tablets 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 ANDA. The "interim" dissolution specifications are as follows:

Dissolution Testing should be conducted in:

Medium: HCl Buffer, pH 2.2
Volume (mL): 900
Apparatus: II (Paddle)
Speed (rpm): 75
Specifications: 1 hr: (b) (4)
4 hr: (b) (4)
8 hr: (b) (4)
20 hr: NLT (b) (4) of the drug is dissolved

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, Shire's Intuniv Extended-release Tablets, is subject to 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"):

U.S. Patent Number	Expiration Date
5,854,290 (the '290 patent)	September 21, 2015
6,287,599 (the '599 patent)	December 20, 2020
6,811,794 (the '794 patent)	July 4, 2022

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 Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 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 these patents within the statutory 45-day period in the United States District Court for the District of Delaware [Shire LLC, Supernus Pharmaceuticals, Inc., Amy F.T. Arnsten, Ph.D., Pasko Rakic, M.D., and Robert D. Hunt, M.D., v. Actavis Elizabeth LLC and Actavis Inc., Civil Action No. 10-cv-00397-UNA]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act,

during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Actavis was the first ANDA applicant to submit a substantially complete ANDA for Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 mg, with a paragraph IV certification. Therefore, with this approval Actavis is eligible for 180-days of generic drug exclusivity for Guanfacine Extended-release Tablets, 1 mg, 2 mg, 3 mg, and 4 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.

As of October 1, 2012, you must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Your ANDA is now subject to the facility fee. You will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid by the date listed in the Federal Register (FR) notice announcing the facility fee amount. If the facility fee is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded your ANDA and all products from facilities that have not paid the appropriate fee. In addition, facilities that have not paid the fee will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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/

GREGORY P GEBA
10/05/2012