



ANDA 079135

Glenmark Generics Inc., USA
U.S. Agent for: Glenmark Generics Ltd.
Attention: William McIntyre, Ph.D.
Executive Vice President, Regulatory Affairs
750 Corporate Drive
Mahwah, NJ 07430

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 24, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Trandolapril and Verapamil Hydrochloride Extended-release Tablets, 1 mg/240 mg. This letter is in regard to this strength only; the 2 mg/180 mg, 2 mg/240 mg and 4 mg/240 mg strengths were previously approved.

Reference is also made to the tentative approval letters issued by this office on January 21 and May 5, 2010, and to your amendment dated June 8, 2010.

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 with respect to the 1 mg/240 mg strength is approved effective on the date of this letter. The Division of Bioequivalence has determined your Trandolapril and Verapamil Hydrochloride Extended-release Tablets, 1 mg/240 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Tarka Tablets, 1 mg/240 mg, of Abbott Laboratories.

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:

Trandolapril: Dissolution testing should be conducted in 500 mL of water at 37°C, USP Apparatus 2 (paddle) at 50 rpm. The test product should meet the following "interim"

specifications: Not less than (b) (4) (Q) of the labeled amount of trandolapril in the dosage form is dissolved in 60 minutes.

Verapamil: Dissolution testing should be conducted in 900 mL of gastric fluid (without pepsin) at pH 1.2 for the first hour, followed by intestinal fluid (without pancreatin) at pH 7.5 for 1-8 hours, USP Apparatus 2 (paddle) with (b) (4), at 50 rpm and 37°C. The test product should meet the following "interim" specifications: 1 hr: (b) (4), 2 hr: (b) (4), 3.5 hr: (b) (4), 5 hr: NLT (b) (4) and 8 hr: Not less than (b) (4) of the labeled amount of verapamil in the dosage form is dissolved.

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.

The reference listed drug (RLD) upon which you have based your ANDA, Abbott's Tarka Tablets, 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. 5,721,244 (the '244 patent) expires on February 24, 2015.

Your ANDA contains a paragraph IV certification under section 505(j) (2) (A) (vii) (IV) of the Act stating that the '244 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Trandolapril and Verapamil Hydrochloride Extended-release Tablets, 1 mg/240 mg, under this ANDA. You notified the agency that Glenmark complied with the requirements of section 505(j) (2) (B) of the Act, and that litigation for infringement of the '244 patent was brought against Glenmark within the statutory 45-day period in the United States District Court for the District of New Jersey [Sanofi-Aventis Deutschland GMBH, Aventis Pharma S.A., Abbott GMBH & Co. KG, and Abbott Laboratories v. Glenmark Generics Inc., USA and Glenmark Generics Limited. Civil Action No. 07-CV-05855 and 08-CV-01658].

Although this litigation remains ongoing, the 30-month period identified in section 505(j) (5) (B) (iii) of the Act, during which

time FDA was precluded from approving you ANDA insofar as it pertains to Trandolapril and Verapamil Hydrochloride Extended-release Tablets, 1 mg/240 mg, has expired. This strength is therefore approved.

With respect to 180-day generic drug exclusivity, we note that Glenmark was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '244 patent. Therefore, with this approval, Glenmark is eligible for 180 days of generic drug exclusivity for Trandolapril and Verapamil Hydrochloride Extended-release Tablets, 1 mg/240 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.

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
Division of Drug Marketing, Advertising, and Communications
5901-B Amundson 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(1)] 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}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- ANDA-79135	----- ORIG-3	----- GLENMARK GENERICIS LTD	----- TRANDOLAPRIL/VERAPAMIL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KEITH O WEBBER
08/30/2010