DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 75-317

DEC 20 2004

Trigen Laboratories, Inc.
Attention: Rajan Embran
207 Kiley Drive
Salisbury, MD 21801

received
12/27/04

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 16, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Terazosin Hydrochloride Capsules, 1 mg (base), 2 mg (base), 5 mg (base), and 10 mg (base).

Reference is also made to your amendments dated July 13, 1998; and June 17, September 7, October 26, and December 6, 2004.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Terazosin Hydrochloride Capsules, 1 mg (base), 2 mg (base), 5 mg (base), and 10 mg (base), to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Hytrin® Capsules 1 mg (base), 2 mg (base), 5 mg (base), and 10 mg (base), respectively, of Abbott Laboratories.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your application, Hytrin® Capsules of Abbott Laboratories, is subject to periods of patent protection. The following patents are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

U.S. Patent No.	Expiration Date
5,212,176 (the '176 patent)	June 29, 2010
5,294,615 (the '615 patent)	April 29, 2013
5,412,095 (the '095 patent)	April 29, 2013

Your application contains paragraph IV patent certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid and will not be infringed by your manufacture, use, or sale of Terazosin Hydrochloride Capsules, 1 mg (base), 2 mg (base), 5 mg (base), and 10 mg (base). Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against the former holder of this ANDA, Warner Chilcott Inc. (Warner Chilcott) for infringement of one or more of the '176,'615, and the '095 patents, which were the subjects of the paragraph IV certifications. This action must have been brought against Warner Chilcott prior to the expiration of forty-five days from the date the notice Warner Chilcott provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). Warner Chilcott previously notified the agency that Warner Chilcott complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for infringement of the '176, '615, or the '095 patent was brought against Warner Chilcott within the statutory forty-five day period. We also note the transfer of ownership from Warner Chilcott to Trigen Laboratories, Inc. occurred in May 2002.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application 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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research