ANDA 75-667 July 28, 2000

Invamed Inc.
Attention: Mahendra Patel, Ph.D.
2400 Route 130 North
Dayton, NJ 08810

Dear Sir:

This is in reference to your abbreviated new drug application dated July 8, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic 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 February 25, April 7, April 19 (2 submissions), and July 21, 2000.

As noted in the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations (19th Edition)", also known as the "Orange Book", the listed drug product (RLD) referenced in your application, Hytrin® Capsules of Abbott Laboratories, is subject to periods of patent protection which expire on June 29, 2010 (U.S. Patent No. 5,212,176), and April 29, 2013 (U.S. Patent Nos. 5,504,207; 5,412,095; and 5,294,615). Your application contains patent certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Invamed Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against Invamed Inc. within the statutory forty-five day period.

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.

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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs

Center for Drug Evaluation and Research