

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74-315

APPROVAL LETTER

DEC 31 1997

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2555 W. Midway Boulevard
P.O. Box 446
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your abbreviated new drug application dated January 12, 1993, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Terazosin Hydrochloride Tablets, 1 mg (base), 2 mg (base), 5 mg (base) and 10 mg (base).

Reference is also made to your amendment dated June 9, 1993; May 3, 1996; and October 14, and December 17, 1998.

The listed drug referenced in your application is subject to periods of patent protection which expire on February 17, 2000 [patent 4,251,532 (the '532 patent)], April 29, 2013 [patents 5,504,207 (the '207 patent), 5,412,095 (the '095 patent), and patent 5,294,615 (the '615 patent)], and June 29, 2010 [patent 5,212,176 (the '176 patent)].

Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the '532, '207, and '095 patents. 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 each patent which is the subject of the certification before the expiration of forty-five days from the date notice provided under paragraph (2)(B)(I) is received. You have notified the Agency that Geneva Pharmaceutical, Inc. (Geneva) complied with the requirements of Section 505(j)(2)(B) of the Act by providing the required notice to each patent holder. You have further informed the Agency that Abbott Laboratories initiated patent infringement suits against Geneva in the United States District Court for the Northern District of Illinois (Eastern Division) involving individual challenges to the '532, '207, and '095 patents, and that the suits involving the '532 patent and the '095 patent were dismissed without prejudice on November 16, 1993 [Civil Action No. 93C 1248(N.D.III)], and February 14, 1996 [Civil Action No. 95C 6657(N.D.III)], respectively. With regard to the '207 patent, you have informed the Agency that on June 4, 1996, Abbott

Laboratories filed a law suit against Geneva [Civil Action No. 96C 3331 (N.D. III)] within forty five days of being notified by Geneva as required under paragraph (2)(B)(I). Furthermore, you have notified the Agency that the 30-month period provided for under 314.107(b)(3) expired on November 4, 1998 and that approval of this abbreviated new drug application should be granted under the regulations.

The Agency acknowledges that in accordance with 21 CFR 314.94 (a)(12)(vi), Geneva is not required to submit patent certifications to the '615 or '176 patents.

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 Tablets 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® Tablets 1 mg (base), 2 mg (base), 5 mg (base), and 10 mg (base), respectively, of Abbott Laboratories, Pharmaceutical Products Division]. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

We would also like to clarify the 180-day exclusivity provisions of the Act with respect to this application. In light of the recent court decisions in Granutec v. Shalala, and Mova v. Shalala, including the district court's order of June 1, 1998 in Mova, declaring the "successful defense" requirement of 21 CFR 314.107(c)(1) invalid, and directing the Agency not to enforce it, the Agency is reinterpreting Section 505(j)(5)(B)(iv). We have determined that Geneva was the first applicant to submit a substantially complete ANDA with a Paragraph IV Certification for this drug product. You were sued as a result of the notice provided to the patent holder/NDA holder as noted above. Thus, you are eligible for 180-days of market exclusivity for this drug product. Such exclusivity will begin to run either from the date Geneva begins commercial marketing, or from the date of a decision of a court finding the referenced patent(s) invalid or not infringed, whichever occurs earlier [Section 505(j)(5)(B)(iv)]. A court decision that can trigger the beginning of exclusivity is a decision of any court in a patent infringement action resulting from a Paragraph IV Certification in which the court finds that the patent is invalid or not infringed. With respect to the "first commercial marketing" trigger for the commencement of 180-day exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner.

Under 21 CFR 314.70, 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,

D. L. Sporn 12/31/98
Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research