

February 11, 2000

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application dated June 6, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Terazosin Hydrochloride Capsules, 1 mg (base), 2 mg (base), 5 mg (base), and 10 mg (base).

Reference is also made to our Tentative Approval letter dated September 28, 1998, and to your amendments dated September 3, 1997; January 30, and February 24, 1998; and February 3, 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 February 17, 2000 (U.S. Patent No. 4,251,532), 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 Paragraph IV Certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that to the best of Mylan's knowledge the patents are invalid, unenforceable or that your manufacture, use, sale, or offer for sale, or importation of Terazosin Hydrochloride Capsules will not infringe on the 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 the patent(s) which are the subject of the certifications before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You informed us that Abbott Laboratories initiated a patent infringement action against you in the United States District Court for the Northern District of Illinois, Eastern

Division, involving a challenge to U.S. Patent No. 5,504,207 only (Abbott Laboratories v. Mylan Pharmaceuticals, Inc., Civil Action No. 97-C-5450 and 98-C-1280). We note that no action was brought against Mylan Pharmaceuticals, Inc. (Mylan) by either the patent holder or NDA holder with regard to the other 4 patents listed in the Paragraph IV Certifications. Subsequent to our issuance of the tentative approval letter, you informed us that Mylan prevailed in the both the district court and in the United States Court of Appeals for the Federal Circuit with respect to the finding that U.S. Patent No. 5,504,207 is invalid.

Furthermore, the Act provides that approval of an abbreviated application that contains a certification described in Section 505(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), and that is for a drug product for which a previous abbreviated application has been submitted which also contains a Paragraph IV Certification, shall be made effective not earlier than one hundred and eighty days after:

1. the date the Secretary receives notice of the first commercial marketing of the drug product under the previous application, or
2. the date of a final decision of a court holding the patent(s) which is the subject of the certification to be invalid or not infringed, whichever event occurs first {Section 505(j)(5)(B)(iv)}.

As noted in "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange Book", an abbreviated new drug application for this drug product was approved for Geneva Pharmaceuticals Inc. (Geneva) on December 31, 1998. This was the first application received by the Agency for this drug product containing a Paragraph IV Certification. Consequently, Geneva became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. According to the "Orange Book", Geneva's market exclusivity expired on February 9, 2000.

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 (Hytrin⁷ 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,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and

Research

