ANDA 75-505

NOV 7 2003

TEVA Pharmaceuticals USA
Attention: Vincent Andolina
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 20, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Loratadine Syrup, 5 mg/5 mL.

Reference is also made to our letter dated November 15, 2002, granting tentative approval to this ANDA, and your amendments dated April 25, June 2, July 22, and October 27, 2003 (2 submissions). We also acknowledge receipt of your correspondence dated October 15, 2002; and August 27, and October 20, 2003, addressing the patent issues noted below.

The listed drug product (RLD) referenced in your application, Claritin® Syrup of Schering Corporation (Schering), is subject to periods of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 4,659,716 (the '716 patent) is scheduled to expire on October 21, 2004, U.S. Patent No. 4,863,931 (the '931 patent) is scheduled to expire on March 15, 2009, and U.S. Patent No. 6,132,758 is scheduled to expire on June 1, 2018.

Your application contains paragraph IV patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that the '716, '931, and '758 patents are invalid or unenforceable, or will not be infringed by your manufacture, use, or sale of Loratadine Syrup 5 mg/5mL. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents that were are subject of the "paragraph IV certifications". This action must be brought against TEVA prior to the expiration of forty-five (45) days from the date the

notice TEVA provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified FDA that TEVA complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, litigation was initiated in the United States District Court for the District of New Jersey involving a challenge to the '716 patent (Schering Corporation v. TEVA Pharmaceuticals USA, Inc., Civil Action No. 99-2237 (JAG)). In a judicial order that was decided, filed, and entered on the Docket on August 8, 2002, the Chief Judge of the United States District Court for the District of New Jersey ruled in a consolidated case (Civil Action No.98-1259 (JWB) et al.) that the contested claims of the '716 patent were invalid. On August 8, 2002, Schering appealed the district court's decision in the consolidated case to the United States Court of Appeals for the Federal Circuit. On August 1, 2003, the United States Court of Appeals for the Federal Circuit affirmed the District Court's prior decision finding the contested claims of the '716 patent to be invalid. Furthermore, the agency recognizes that the 30-month period identified in Section 505(j)(5)(iii) of the Act, during which time FDA was precluded from approving your application, has expired. In addition, we note that no action was brought by either the patent holder or NDA holder against TEVA within the 45-day period with regard to the '931 or '758 patents. Furthermore, we note that no action was brought within the 45-day period by either the patent holder or NDA holder against TEVA with respect to TEVA's recertification and renotification regarding the '716, '931, and '758 patents following reformulation of the drug product.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Loratadine Syrup, 5 mg/5 mL, to be bioequivalent to the listed drug, Claritin® Syrup, 5 mg/5 mL, of Schering Corporation.

We note that TEVA was the first ANDA applicant to submit a substantially complete ANDA containing a paragraph IV certification to the '716, '931, and '758 patents. Therefore, with this approval, TEVA is eligible for 180-days of market exclusivity for Loratadine Syrup, 5 mg/5 mL. With respect to the '716 patent, this exclusivity was triggered on the date of the appellate court decision, August 1, 2003. With respect to the '931 and '758 patents, your exclusivity will begin to run on the date TEVA begins commercial marketing of the drug product.

Please refer to 21 CFR 314.107(c)(4) for further clarification of the "first commercial marketing" trigger for the commencement of the 180-day exclusivity. The agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this drug product.

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.

Sincerely yours,

(b)(6)

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

APPEARS THIS WAY
ON ORIGINAL