ANDA 75-822 February 10, 2003

Wyeth Consumer Healthcare
Attention: David Smith
5 Giralda Farms
Madison, NJ 07940

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 9, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Loratadine Orally Disintegrating Tablets, 10 mg (OTC).

Reference is also made to your amendments dated December 12, 2000; January 21, January 22, October 17, December 10, December 13, and December 18, 2002; and January 10, 2003. We also refer to your correspondence dated June 8, and August 1, 2000; and September 5, 2002 addressing patent issues related to the reference listed drug product (RLD).

The listed drug product (RLD) referenced in your application, Claritin® Reditabs™ 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, and U.S. Patent No. 4,863,931 (the '931 patent) is scheduled to expire on May 15, 2009. Your application contains paragraph IV certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Loratadine Orally Disintegrating Tablets, 10 mg, will not infringe the claims of the '716 and '931 patents. 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 Wyeth Consumer Healthcare (Wyeth) for infringement of either the '716 or '931 patents that were the subject of the paragraph IV certifications. This action must be brought against Wyeth prior to the expiration of forty-five (45) days from the date the notice provided by Wyeth to the NDA/patent holder(s) under paragraph (2)(B)(i) was received by the patent/NDA holder(s).

You have notified the agency that Wyeth complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, in June, 2000, Schering initiated a patent infringement suit involving certain claims of Schering's '716 patent against you in the United States District Court for the District of New Jersey (Schering Corporation v. American Home Products Corp., Wyeth-Ayerst Laboratories and ESI-Lederle, Civil Action No. 00-2944(JAG)). In an order dated August 8, 2002, and entered August 12, 2002, the Chief Judge of the United States District Court for the District of New Jersey granted the defendant's motion for summary judgment, ruling that the contested claims of the '716 patent were invalid. These were the only claims in this case. On August 8, 2002, Schering Corporation appealed this decision to the United States Court of Appeals for the Federal Circuit where it is currently pending.

The Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired as to the '716 patent. We also note that no action was brought against Wyeth by either the patent holder or the NDA holder with regard to the '931 patent.

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 Orally Disintegrating Tablets, 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Claritin® Reditabs™, 10 mg, of Schering Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

With respect to 180-day generic drug exclusivity, we note that Wyeth was the first applicant to submit a substantially complete ANDA containing paragragh IV certification to the '716 and '931 patents. Therefore, with this approval Wyeth is eligible for 180-days of market exclusivity for this drug product with respect to the '716 and '931 patents, as provided for under Section 505 (j)(5)(B)(iv) of the Act. With respect to the '716 and '931 patents, such exclusivity will begin to run on the earlier of either (1) the date Wyeth begins commercial marketing of its Loratadine Orally Disintegrating Tablets, 10mg, or (2) with respect to each patent, the date of a decision of the appellate court affirming the decision of the district court that the contested claims of the '716 and '931 patents are invalid, unenforceable, or not infringed.

With respect to the "first commercial marketing" trigger for the commencement of 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. Please submit correspondence to your application stating the date you commence commercial marketing of this product.

If you have any questions concerning the effective date of approval of an ANDA and the elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998, Federal Register (Volume 63, No. 214, at p. 59710).

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,

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