ANDA 75-209 January 21, 2003

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2555 W. Midway Boulevard
Broomfield, CO 80038-0466

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 24, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Loratadine Tablets, 10mg (OTC).

Reference is also made to our Tentative Approval letter dated October 22, 2001, and to your amendments dated September 4, 1998; May 3, 1999; November 27, 2000; May 9, 2001; April 19, May 2, May 29, June 28, October 11, November 8, November 26, December 4, December 5, December 13, and December 16, 2002; and January 3, and January 13, 2003.

The listed drug product referenced in your application (RLD), Claritin Tablets, 10 mg, of Schering Corporation (Schering), is subject to periods of patent protection that expire on October 21, 2004 (U.S. Patent No. 4,659,716, the '716 patent), and March 15, 2009 (U.S. Patent No. 4,863,931, the '931 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 Loratadine Tablets, 10 mg, will not infringe on the claims of the '716 patent, or that the claims of the '716 patent are otherwise invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Geneva for infringement of one or more of the patents that are the subject of the certifications. This action must be brought against Geneva prior to the expiration of forty-five (45) days from the date the notice provided by Geneva under Section 505(j)(2)(B)(i) is received by the patent and NDA holders. You have notified the Agency that Geneva complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, in March 1998, Schering initiated a patent infringement suit against you in the United States District Court for the District of New Jersey (Schering Corporation v. Geneva Pharmaceuticals, Inc. and Novartis Corporation, Civil Action No. 2:98cv01259 (JAG)).

Similar patent infringement cases brought against multiple defendants were subsequently consolidated into a single case. See Schering Corporation v. Geneva Pharmaceuticals, Inc. and Novartis Corporation, Civil Action Number 98-1259-JWB. Also sued were TEVA Pharmaceuticals USA, Inc., 98-2237-JWB and 00-255-JWB; Zenith Goldline Pharmaceuticals, Inc., 99-2820JWB; Andrx Corporation, et al., 00-1439-JWB; Mylan Pharmaceuticals, Inc., 00-1657-JWB; American Home Products, et al., 00-2944-JWB; and IMPAX Laboratories, Inc., 01-9, 01-279-JWB, 01-520-JWB. In an order dated August 8, 2002, the Chief Judge of the United States District Court for the District of New Jersey granted the defendants' motions for summary judgement, ruling that the contested claims of the '716 patent were invalid. 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 the agency was precluded from approving your application, has expired as to the '716 patent.

Furthermore, we note that, although the '931 patent was issued on September 5, 1989, it was not listed with the agency by the NDA holder until October 3, 1997. The Office of Generic Drugs accepted your application for filing on September 25, 1997. Thus, pursuant to 21 CFR 314.94(a)(12)(vi), Geneva is not required to file an amended patent certification to address 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 Tablets, 10 mg, to be bioequivalent to the listed drug Claritin® Tablets, 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 Geneva was the first applicant to submit a substantially complete ANDA containing a paragraph IV certification to the '716 patent. Therefore, with this approval, Geneva is eligible for an initial 180-days of market exclusivity for this drug product with respect to the '716 patent, as provided for under Section 505(j)(5)(B)(iv) of the Act. Such exclusivity will begin to run on the earlier of either (1) the date Geneva begins commercial marketing of its Loratadine Tablets, 10 mg, or (2) the date of a

decision of the appellate court affirming the decision of the district court that the contested claims of the‘716 patent 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 this ANDA stating the date you commenced commercial marketing of the drug 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