ANDA 76-050 January 30, 2003

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw
30831 Huntwood Avenue
Hayward, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 12, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Loratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation) (OTC).

Reference is also made to our Tentative Approval letter dated May 29, 2002, and to your amendments dated April 26, 2001; and October 11, December 4, December 23, and December 27, 2002.

The listed drug product (RLD) referenced in your application, Claritin-D® 12-Hour Extended-release Tablets 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 4,659,716 (the '716 patent) is scheduled to expire on October 21, 2004, and U.S. Patent 4,863,931 (the '931 patent) is scheduled to expire on March 15, 2009. 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 and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation), will not infringe on the claims of the '716 or '931 patents, or that the claims of both patents are invalid or unenforceable. 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 IMPAX Laboratories, Inc. (IMPAX) for infringement of either the '716 or '931 patents that were the subject of the paragraph IV certifications. This action must be brought against IMPAX prior to the expiration of forty-five (45) days from the date the notice provided by IMPAX under Section 505(j)(2)(B)(i) is received by the patent and NDA holders.

You have notified the Agency that IMPAX complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, in February 2001, Schering initiated a patent infringement suit involving Claims 1 and 3 of Schering's '716 patent against you in the United States District Court for the District of New Jersey (Schering Corporation v. IMPAX Laboratories, Inc., Civil Action No. 01CV-0520-JWB). 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 judgement, ruling that the contested claims of the '716 patent were invalid. These were the only claims in this case. Reference is made to FDA regulations at 21 C.F.F. 314.107, and in the FDA Guidance published in March 2000 entitled "Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act". With respect to ANDAs such as this one submitted after the March 2000 guidance was issued, an application may be approved and 180-day exclusivity triggered under Section 505(j)(5)(B)(iv)(II) of the Act as of the date the district court enters its decision that the patent is invalid or not infringed. We also note that on August 8, 2002, Schering Corporation appealed the district court's decision to the United States Court of Appeals for the Federal Circuit where it is currently pending.

We note that no action was brought against IMPAX 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 and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation), to be bioequivalent to the listed drug, Claritin-D® 12-Hour Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation) of Schering Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution tests and tolerances are:

> The dissolution testing should be conducted in 900 mL of 0.1N HCl for one hour, then the medium should be replaced with 900 mL of 0.05M phosphate buffer at pH 8.2 containing 0.01% sodium lauryl sulfate (SLS) at 37°C using USP 24 apparatus II (paddle) at 50 rpm. Loratadine and Pseudoephedrine test products should meet the following "interim" specifications:

For Loratadine:

NLT [ ] (Q) dissolved in 60 minutes

For Pseudoephedrine:

1 Hour	[ ]
4 Hours	[ ]
12 Hours	[ ]

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data from the first three production size batches in a supplemental application. A "Special Supplememt – Changes Being Effected" (CBE-0) should be submitted when there are no revisions to be proposed to the "interim" specifications or the proposed final specifications are tighter than the "interim" specifications. In all other instances, a Prior Approval Supplement should be submitted.

With respect to 180-day generic drug exclusivity, we note that IMPAX was the first applicant to submit a substantially complete ANDA containing paragraph IV certifications to the '716 and '931 patents for this drug product. Therefore, with this approval, IMPAX 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 patent, this exclusivity began to run on the date of entry of the District Court decision referenced above, August 12, 2002. With respect to the '931 patent, such exclusivity will begin to run on the earlier of either (1) the date IMPAX begins commercial marketing of its Loratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/120 mg (12-Hour Formulation), or (2) the date of the decision or order by a court holding that the '931 patent is invalid, unenforceable, or not infringed.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107c)(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