ANDA 74-752

JUL 9 1998

Andrx Pharmaceuticals, Inc.
Attention: David A. Gardner
4001 S.W. 47th Avenue, #201
Fort Lauderdale, FL 33314

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 22, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for CARTIA XT (Diltiazem Hydrochloride Extended-release Capsules, USP); 120 mg, 180 mg, 240 mg and 300 mg.

Reference is also made to your amendments dated February 18 and 26, May 8, June 2 and 25, 1998.

The listed drug product referenced in your application is subject to a period of patent protection as follows:

Patent No. 5,470,584 - Expires May 20, 2011
Patent No. 5,439,689 - Expires August 8, 2012
Patent No. 5,364,620 - Expires November 14, 2011
Patent No. 5,286,497 - Expires May 20, 2011
Patent No. 5,002,776 - Expires March 26, 2008
Patent No. 4,894,240 - Expires January 16, 2007

Your application contains a patent certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Diltiazem Hydrochloride Extended-release Capsules will not infringe on the patent or that the patent is otherwise invalid. You also included in your application notice to each patent holder as required under section 505(j)(2)(B)(I). You further informed the Agency that Hoechst Marion Roussel Inc. initiated a patent infringement suit (Patent No. 5,470,584) against you in United States District Court for the Southern District of Florida(Hoechst Marion Roussel, Inc. and Carderm Capital L.P. v. Andrx Pharmaceuticals, Inc., Civil Action No. 96-06121-CIV-Roettger) within the 45 day period described in section 505(j)(5)(B)(iii), thereby triggering the 30 month period identified in that section. The 30-month period identified in section 505(j)(5)(B)(iii) has now expired.

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 CARTIA XT (Diltiazem Hydrochloride Extended-release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Cardizem CD Capsules, 120 mg, 180 mg, 240 mg and 300 mg of Hoechst Marion Roussel Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Andrx was the first applicant to submit a substantially complete ANDA with a section 505(j)(2)(A)(vii)(IV) ("paragraph IV") certification and thus is eligible for 180 days of market exclusivity. Such exclusivity will begin to run either from the date Andrx begins commercial marketing, or from the date of a decision of a court finding the patent invalid or not infringed, whichever is earlier (Section 505(j)(5)(B)(iv) of the Act). Please note that you are required to inform the Office of Generic Drugs of a relevant court order and judgement under 21 CFR 314.107(e)(2)(iv) and of the date that you commence commercial marketing of this drug product under 21 CFR 314.107(c)(4).

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.

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,

7/9/98

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