DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-608

DEC 3 2004

Andrx Pharmaceuticals, LLC
Attention: Jennifer Spokes
2945 W. Corporate Lakes Blvd.
Weston, FL 33331

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 27, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fosinopril Sodium and Hydrochlorothiazide Tablets, 10 mg/12.5 mg, and 20 mg/12.5 mg.

Reference is also made to your amendments dated April 14, April 23, June 23, July 29, and August 27, 2004. We also acknowledge receipt of your correspondence dated June 10, 2003, and September 20, 2004, addressing the patent issues noted below.

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 Fosinopril Sodium and Hydrochlorothiazide Tablets, 10 mg/12.5 mg, and 20 mg/12.5 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Monopril HCT® Tablets 10 mg/12.5 mg and 20 mg/12.5 mg, respectively, of Bristol Myers Squibb. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your application, Monopril HCT® Tablets of Bristol Myers Squibb, is subject to a period 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. 5,006,344 (the '344 patent) will expire on January 10, 2010. Your application contains a paragraph IV patent certification to the '344 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '344 patent will not be infringed by your

manufacture, use, or sale of Fosinopril Sodium and Hydrochlorothiazide Tablets, 10 mg/12.5 mg and 20 mg/12.5 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Andrx Pharmaceuticals, LLC (Andrx) for infringement of the '344 patent which was the subject of the paragraph IV certification. This action must have been brought against Andrx prior to the expiration of forty-five days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Andrx complied with the requirements of Section 505(j)(2)(B) of the Act, and that litigation was brought against Andrx in the United States District Court for the Southern District of Florida involving your challenge to the '344 patent [Bristol-Myers Squibb Company and E.R. Squibb & Sons, LLC v. Andrx Pharmaceuticals, LLC and Andrx Pharmaceuticals, Inc., Civil Action No. 03-06703-CIV]. You have also informed the Agency that on June 4, 2004, the district court ruled that Andrx's drug product does not infringe the '344 patent, and that the plaintiff's opportunity to appeal the court decision has expired. Thus, there are no patent issues to block approval of your application.

We note that Andrx was the first ANDA applicant to submit a substantially complete ANDA containing a paragraph IV certification to the '344 patent. Therefore, with this approval, Andrx is eligible for 180 days of market exclusivity for Fosinopril Sodium and Hydrochlorothiazide Tablets, 10 mg/12.5 mg and 20 mg/12.5 mg. This exclusivity began on the date of the district court decision, June 4, 2004.

Under Section 506A of the Act, 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 final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 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 FDA 2253 at the time of their initial use.

(b)(6)

Sincerely yours,

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