DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-267

FEB 11 2004

Andrx Pharmaceuticals, LLC
Attention: William Stahovec
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Benazepril Hydrochloride Tablets, 5 mg, 10 mg, 20 mg, and 40 mg.

Reference is also made to the Tentative Approval letter issued on February 26, 2003, and to your amendments dated March 21, 2002; March 5, April 15, November 7, November 20, and December 1, 2003; and January 30, 2004.

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 Benazepril Hydrochloride Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lotensin® Tablets 5 mg, 10 mg, 20 mg, and 40 mg, respectively, of Novartis Pharmaceuticals Corp.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

Sincerely yours,

(b)(6) [redacted]

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