DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-820/S-003, S-004

Amneal Pharmaceuticals
Attention: Alpesh Patel
US Agent for Biokey, Inc.
75 Adams Avenue
Hauppauge, NY 11788

Dear Sir:

This is in reference to your supplemental new drug application dated January 29, 2009, submitted under section 505 (j) of the Federal Food, Drug and Cosmetic Act, regarding your abbreviated new drug application for Benazepril Hydrochloride Tablets USP, 5 mg, 10 mg, 20 mg and 40 mg.

Reference is also made to your amendments dated February 23, June 1, and June 22, 2009.

These supplemental applications, submitted as "Supplements: Changes Being Effected in 30 Days", provide for:

S-003 A facility addition with batch scale-up provision: Amneal Manufacturing facility, manufacturing, packaging, testing (Drug substance and excipients in Brookhaven, NY).

S-004 Labeling

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Paul Schwartz
7/23/2009 12:11:20 PM
Signed for R. Patel