DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-374

MAR 31 2004

Amide Pharmaceutical, Inc.
Attention: Jasmine Shah
101 East Main Street
Little Falls, NJ 07424

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 7, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Quinaretic Tablets [Quinapril Hydrochloride and Hydrochlorothiazide Tablets], 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 mg.

Reference is also made to your amendments dated May 16, June 13, July 2, and September 29, 2003; and January 19, and March 10, 2004. We acknowledge receipt of your correspondence dated August 16, 2002, addressing the patent issue 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 Quinaretic Tablets [Quinapril Hydrochloride and Hydrochlorothiazide Tablets], 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 mg), to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Accuretic® Tablets 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 mg, respectively, of Pfizer Pharmaceuticals Ltd. 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, Accuretic® Tablets 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 mg, of Pfizer Pharmaceuticals Ltd. 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. 4,743,450 (the '450 patent) is scheduled to expire on August 24, 2007. Your application contains a patent certification to the '450 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '450 patent is invalid and/or unenforceable, and/or will not be infringed by your manufacture, use, or sale of Quinapril Hydrochloride and Hydrochlorothiazide Tablets, 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 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 is brought against Amide Pharmaceutical, Inc. (Amide) for infringement of the '450 patent which was the subject of the paragraph IV certification. This action must be brought against Amide prior to the expiration of forty-five days from the date the notice Amide provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the Agency that Amide complied with the requirements of Section 505(j)(2)(B) of the Act, and that no legal action for infringement of the '450 patent was brought against Amide within the statutory forty-five day period.

With this approval, Amide is eligible for 180-day generic drug marketing exclusivity for Quinapril Hydrochloride and Hydrochlorothiazide Tablets, 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 mg as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the Agency has concluded that Amide was the first ANDA applicant to submit a substantially complete ANDA for Quinapril Hydrochloride and Hydrochlorothiazide Tablets, 10 mg (base)/12.5 mg, 20 mg (base)/12.5 mg, and 20 mg (base)/25 mg, containing a paragraph IV certification to the '450 patent. This exclusivity will begin to run from the date of first commercial marketing of the drug product.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commenced commercial marketing of this product.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's 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, 59710).

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