ANDA 40-283 December 29, 1998

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 dated October 27, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Carisoprodol, Aspirin and Codeine Phosphate Tablets USP, 200 mg/325 mg/16 mg.

Reference is also made to your amendments dated January 1, June 3, and December 5, 1998.

The listed drug referenced in your application is subject to a period of patent protection which expires on August 12, 2002 (patent 4,534,974 [the '974 patent]). 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 this drug product will not infringe on the '974 patent, and that the '974 patent is invalid and/or unenforceable. Section 505(j)5)B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified FDA that Amide Pharmaceutical, Inc. (Amide) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Amide within the statutory forty-five day period.

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 Carisoprodol, Aspirin and Codeine Phosphate Tablets USP, 200 mg/325 mg/16 mg, respectively, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Soma Compound with Codeine Tablets, 200 mg/325 mg/16 mg, respectively, of Wallace Pharmaceuticals). Your dissolution testing should be incorporated into the stability and quality

control program using the same method proposed in your application.

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,

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