ANDA 74-988 April 30, 1999

Jerome Stevens Pharmaceuticals, Inc.
Attention: Ronald J. Steinlauf
60 DaVinci Drive
Bohemia, NY 11716

Dear Sir:

This is in reference to your abbreviated new drug application dated October 21, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Orphenadrine Citrate, Aspirin, and Caffeine Tablets, 25 mg/385 mg/30 mg, and 50 mg/770 mg/60 mg.

Reference is also made to your amendments dated September 10, and October 13, 1998; and April 1, 1999.

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 that your Orphenadrine Citrate, Aspirin, and Caffeine Tablets, 25 mg/385 mg/30 mg, and 50 mg/770 mg/60 mg, are bioequivalent, and, therefore, therapeutically equivalent, to the listed drugs (Norgesic^{R} Tablets 25 mg/385 mg/30 mg, and Norgesic^{R} Forte Tablets, 50 mg/770 mg/60 mg, respectively, of 3M Pharmaceuticals, Inc.).

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. 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, at the time of their initial use, be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253.

Sincerely yours,

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